S. HRG. 100-148

# PROCESS PATENT LEGISLATION

## HEARING

BEFORE THE

SUBCOMMITTEE ON
PATENTS, COPYRIGHTS AND TRADEMARKS

OF THE

## COMMITTEE ON THE JUDICIARY
## UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

ON

**S. 568**

PROCESS PATENT AMENDMENTS ACT OF 1987

**S. 573**

PROCESS PATENT ACT OF 1987

AND

**S. 635**

OMNIBUS INTELLECTUAL PROPERTY RIGHTS IMPROVEMENT ACT OF 1987

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APRIL 22, 1987

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**Serial No. J-100-17**

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# PROCESS PATENT LEGISLATION

WEDNESDAY, APRIL 22, 1987

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS,
*Washington, DC.*

The Subcommittee on Patents, Copyrights and Trademarks met, pursuant to notice, at 9:31 a.m., in room 226, Dirksen Senate Office Building, Hon. Dennis DeConcini (chairman of the subcommittee) presiding.

Also present: Senators Hatch and Grassley.

Staff present: Ed Baxter, chief counsel; Tara McMahon, majority counsel; and Cecilia Swensen, legislative aide.

## OPENING STATEMENT OF HON. DENNIS DeCONCINI, A U.S. SENATOR FROM THE STATE OF ARIZONA, CHAIRMAN, SENATE JUDICIARY SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS

Senator DECONCINI. The subcommittee will come to order.

I am very pleased to be chairing a hearing on the issue of how best to provide improved patent protection for the patented process by which products are manufactured.

The United States' competitiveness depends upon an effective patent system which keeps pace with rapidly emerging technology. Our laws must enable U.S. companies to protect themselves from the foreign manufacturers which steal American-owned technology and then use American innovations to compete with U.S.-manufactured products.

Under today's system, U.S. process patent owners can prevent the unauthorized use of their process in the United States. However, under the current patent laws, they cannot prevent the unauthorized use of their process outside the United States, nor can they prevent sale in the United States of products made by their process.

The proposed legislation would give patent owners the ability to sue for damages and an injunction in Federal district court when someone uses or sells in the United States, or imports into the United States, a product made by their patent process.

I believe that there is basic agreement that our patent laws should be amended to provide this improved protection, but there remains a disagreement on some details of the proposed law. S. 568 is identical to S. 1543, which was unanimously passed by the Senate Judiciary Committee and the full Senate in the 99th Congress.

S. 1543 was a compromise among the diverse groups which saw the need for a proper balance between the improved patent protection and the innocent non-manufacturing purchasers who might be adversely affected by the new protection. Many of the members of that compromise process are here today, and I applaud those who have continued to go forward in our efforts to find a solution to this problem.

When my colleague from Utah, Senator Hatch, and I introduced S. 568 to this Congress, we stated that fair process patent protection was among the highest priorities of this Congress as far as we were concerned. I also stated that it would be foolish of me to believe that we could not improve upon the efforts of the last Congress.

I am eager to work with the various groups in reaching a new compromise, and I am hopeful that today's hearings will clarify the remaining disputes and allow the subcommittee to make informed decisions on the issues.

Two additional process patent bills have been introduced this Congress, S. 573 and S. 635. I know that Senator Lautenberg, who introduced S. 573, is as committed as I am to working toward a fair compromise bill that can become law in this 100th Congress. He, too, seeks a balanced bill that addresses the concerns of affected parties while providing needed enhancement of the rights of American innovators. I commend him for his efforts and his staff for their continued capability and willingness to work with our staff to find a compromise in this area.

The administration also sees the need for process patent reform and has proposed legislation in the President's trade package. I am eager to hear their views and suggestions on how we can achieve the goal that we all have in mind.

I intend to go forward in this subcommittee and in the full committee with legislation providing greater protection to patent processers. I believe that the major interest groups with opinions on process patent legislation are represented today at these hearings, and I am looking forward to hearing their testimony.

Let me say at the outset that I am interested in hearing constructive comments, and I am sure that is what we will hear today. I hope that the witnesses are prepared to tell the committee what they think needs to be done to improve this legislation.

Quite frankly, I am not too interested in going back over old ground from the last Congress and hearing about who did what to whom and why. What I am looking for are constructive solutions and suggestions that we can enact into law.

I propose that the parties join me today with their commitment to work together. My staff is available, as I know Senator Hatch's staff is, to work out a compromise. I am personally committed to sit and visit if necessary to work toward this solution.

I am very pleased to yield to my colleague, the ranking member, Senator Hatch from Utah.

**STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH, MEMBER, SENATE JUDICIARY SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS**

Senator HATCH. Thank you, Mr. Chairman, Senator DeConcini.

I want to thank you for holding this timely hearing on the process patent legislation which is proposed here in the Senate. Of course, the chairman and I introduced S. 568 to modernize U.S. process patent law.

The Process Patent Amendments Act of 1987 contains the same language as S. 1543, as Senator DeConcini has pointed out, that passed the Judiciary Committee and the Senate unanimously during the 99th Congress.

A serious threat to American business exists under current process patent law in that foreign companies are permitted to pirate American process patents and then sell the product in the United States. In short, use of the patented process outside the United States does not infringe the U.S. patent law, nor does the sale of products made by the patented process.

So S. 568 prohibits the importation, the use or sale of products which are produced by a process of manufacture protected by a U.S. patent.

Certainly, all of us here today share the goal of this legislation: protecting American business interests from exploitation by foreign corporations.

In each of the Senate process patent bills, U.S. manufacturers will be responsible for assuring that materials they receive from foreign suppliers are not made by a process that violates a U.S. patent. This is as it should be. However, S. 568 also recognizes that a process patent bill not carefully drafted can invite the potential for market intimidation of an innocent, unknowing infringing retailer or importer.

Therefore, S. 568 also includes limited protection for such innocent infringers by permitting them to make a request for disclosure to a process patent holder or licensee before purchasing goods that may have been made without authorization by his patented process.

If the patent holder then brings a suit and shows that the products were made with his process, the infringer is entitled to a grace period from the time of notice to sell or use prenotice inventory, subject only to reasonable royalties.

While the various bills differ in many respects, we are working to achieve a fair compromise. I want to commend Senator Lautenberg—and welcome him to this committee—and the chairman for their diligent efforts in working to resolve these differences.

It is important for each of us to keep in mind that we are working in somewhat of a tight time frame in coming to an agreement on this legislation in that it will be included in the trade bill.

I look forward to hearing the specific views of the witnesses here and would like to take this opportunity to thank each and every one of them for coming and for participating in this process.

Mr. Chairman, I appreciate your holding these hearings and look forward to listening to a number of the witnesses today.

Senator DECONCINI. Thank you, Senator Hatch.

You have been a great asset, and your staff has, too, in working on this compromise last year, and I think we can put something together early in this Congress.

The Senator from Iowa?

**OPENING STATEMENT OF HON. CHARLES E. GRASSLEY, A U.S. SENATOR FROM THE STATE OF IOWA, MEMBER, SENATE JUDICIARY SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS**

Senator GRASSLEY. Mr. Chairman, I, too, thank you for holding these hearings because it is a very serious problem that we are dealing with here, and I am glad that there is a growing consensus that legislation needs to be enacted in the necessary area of process patent protection, particularly abroad.

There, of course, is something very inherently unfair about U.S. research-based industries pouring resources into a product or a process patent and then having that product or process pirated abroad and shipped back into this country for sale. The inventor, of course, is required to disclose his or her process patent, and it is available in the Patent Office just like some recipe in a cookbook for all to see.

It just seems to me that protecting America's intellectual property or software or semiconductors or pharmaceuticals and our computer designs that give America a technological edge in the world marketplace has to be a very important part of the trade agenda.

I know that you, Mr. Chairman, approach that not only from the standpoint of protecting inventions but also from the standpoint of how it does affect our trade agenda, and I think that it is very necessary that this legislation be passed.

I thank you, Mr. Chairman, for the leadership that you have demonstrated in the recognition of this as not only a trade problem but an intellectual property rights problem.

Senator DECONCINI. Thank you, Senator Grassley.

At this point, I will place into the record copies of S. 568, S. 573, and S. 635.

II

100TH CONGRESS
1ST SESSION

# S. 568

To protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 19, 1987

Mr. HATCH (for himself and Mr. DECONCINI) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

---

# A BILL

To protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That this Act may be cited as the "Process Patent Amendments Act of 1987".

SEC. 2. (a) Section 154 of title 35, United States Code, is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others, to the extent provided in section 271(a)(2), from using or selling products produced thereby throughout the United

States, or importing products produced thereby into the United States,".

(b) Section 271 of title 35, United States Code, is amended by—

(1) inserting "(1)" after "(a)";

(2) adding at the end of subsection (a), the following:

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product produced by such process, infringes the patent. A product will no longer be considered to have been produced by a patented process once it has been materially changed by subsequent steps or processes.".

(c) Section 287 of title 35, United States Code, is amended by—

(1) striking out "Limitation on damages" in the section heading and inserting in lieu thereof "Limitation on damages and other remedies";

(2) inserting "(a)" before "Patentees,"; and

(3) adding at the end thereof the following new subsection:

"(b)(1) An infringer under section 271(a)(2) shall be subject to all of the provisions relating to damages and injunctions set forth in this title except to the extent that those

remedies are limited by this subsection or section 3 of the Process Patent Amendments Act of 1987. The limitations on remedies set forth in this subsection shall not be available to any party who—

"(A) engaged in the actual practice of the patented process;

"(B) is owned or controlled by the party who engaged in the actual practice of the patented process;

"(C) owns or controls the party who engaged in the actual practice of the patented process;

"(D) having made a request for disclosure as provided in subsection (b)(5), fails to notify its supplier of patents identified in response to the request and to instruct its supplier to refrain from infringement of such patents; or

"(E) had knowledge prior to the infringement that a patented process was used to produce the product whose importation, use, or sale constituted the infringement.

"(2) No damages shall be recovered by the patentee unless the infringer had notice of the infringement and continued to infringe thereafter. Damages may be recovered only for infringement that occurred after notice of infringement.

"(3) No remedy may be obtained during the eighteen months after the date of notice for retail sales of a normal

volume of products in inventory or on order at the time of notice, obtained from a party in the United States who did not use the patented process, provided the retailer discloses to the patentee, within 30 days from notice, the identity and location of the party from whom the products were purchased. Normal quantity of products in inventory and on order shall be determined by previous business practices, and could include units of a product ordered prior to notice and received within a period not to exceed eighteen months after notice.

"(4) The remedy for the importation, use, or sale of units of the infringing product ordered prior to notice and imported, used, or sold in a manner consistent with the normal business practices of the infringer during the six months after the date of notice shall be limited to a reasonable royalty. The limitation in this subparagraph shall not be available to any party who failed to make a request for disclosure, as defined in subparagraph (5), of the party asserting infringement or its licensee.

"(5)(A) For purposes of this paragraph, a 'request for disclosure' means a written request made to a party then engaged in the manufacture of a product to identify all process patents owned by or licensed to that party as of the time of the request that could reasonably be asserted to be infringed under section 271(a)(2) if that product were imported

into, or sold or used in, the United States by an unauthorized party. A request for disclosure is further limited to a request—

"(i) made by a party regularly engaged in the sale of the same type of products as the party to whom the request is directed, or a request which includes facts showing that the requester plans to engage in the sale of such products; and

"(ii) made prior to such party's first use importation, or sale of units of the product produced by an infringing process and prior to notice of infringement.

"(B) In any action where the infringer made a request for disclosure from the party asserting infringement and the infringed patent was not identified within 60 days, the remedy for the importation, use, or sale of units of the infringing product which are imported, used, or sold by the infringer in a manner consistent with the normal business practices of the infringer during the eighteen months after the date of notice shall be limited to a reasonable royalty.

"(C) For the purposes of the limitations on remedies in this subsection—

"(i) no party may make more than one request for disclosure of the same party for the identification of process patents for producing a particular product; and

"(ii) no party who has received the benefit of the limitations of this paragraph or paragraph (4) with respect to the infringement of one process patent shall be entitled to that benefit in the event of a subsequent infringement of any process patent for producing the same product owned by the same patentholder at the time of the first infringement.

"(6) For the purposes of the remedy limitations in subsection (b), notice of infringement means actual knowledge, or receipt of notification, that a product was produced by a patented process without authorization of the patentee. A notification shall constitute notice of infringement only if it is in writing and sets forth facts which are sufficient to establish that there is a substantial likelihood that the product was made by the infringing process. Filing an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of a notification.".

(d) The table of sections for chapter 29 of title 35, United States Code, is amended by amending the item relating to section 287 to read as follows:

"287. Limitations on damages and other remedies; marking and notice.".

SEC. 3. (a) This Act and the amendments made by this Act shall apply only to products produced or imported after the date of enactment, and shall not abridge or affect the right of any persons or their successors in business to contin-

ue to use, sell or import any specific product already in substantial and continuous sale or use in the United States on July 1, 1986, or for which substantial preparation for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date.

(b) This Act and the amendments made by this Act shall not deprive a patent owner of any other remedies available under section 271 of title 35, United States Code, section 337 of the Tariff Act of 1930, or any other provision of law.

SEC. 4. Beginning on the date one year after the date of enactment of this Act and each year for 4 additional years thereafter, the Department of Commerce shall submit an annual report to the Congress on the effect of this Act and the amendments made by this Act, on the importation of ingredients to be used for manufacturing products in the United States in those domestic industries that submit formal complaints to the Department alleging that their legitimate sources of supply have been adversely affected.

SEC. 5. (a) Chapter 29 of title 35, United States Code, is amended by adding at the end thereof the following:

**"§ 295. Presumption: product produced by patented process**

"In actions alleging infringement of a process patent based on use, sale, or importation of a product produced by

the patented process, if the court finds (1) that a substantial likelihood exists that the product was produced by the patented process and (2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so produced, and the burden of establishing that the product was not produced by the process shall be on the party asserting that it was not so produced.".

(b) The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: product produced by patented process.".

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II

100TH CONGRESS
1ST SESSION

# S. 573

To protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 19, 1987

Mr. LAUTENBERG introduced the following bill; which was read twice and referred to the Committee on the Judiciary

---

# A BILL

To protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That this Act may be cited as the "Process Patent Act of 1987".

SEC. 2. (a) Section 154 of title 35, United States Code, is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling products produced thereby throughout, or importing products produced thereby into, the United States,".

(b) Section 271 of title 35, United States Code, is amended by—

(1) inserting "(1)" after "(a)";

(2) adding at the end of subsection (a), the following:

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product produced by such process infringes the patent. A product which is made by a patented process will, for the purposes of this title, not be considered to be so made if, prior to importation into the United States, it is materially changed by subsequent processes.".

(c) Section 287 of title 35, United States Code, is amended by—

(1) inserting "(a)" before "Patentees,"; and

(2) adding at the end thereof the following new subsection:

"(b)(1) No damages shall be recovered by the owner of the process patent rights for infringement under section 271(a)(2) of this title from an infringer who did not use the patented process unless the infringer had notice of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. For purposes of this subsection,

'notice' means actual knowledge, or receipt of notice, that a product was produced by a patented process without authorization of the owner of the process patent rights. A notice under this subsection shall specify the patented process or processes claimed to have been used, and the reasons for belief that such process or processes were used in the production of the product. Filing of an action for infringement shall constitute such notice if the pleadings or other papers contain such specifications.

"(2) The court before which an action is brought under section 271(a)(2) may provide for the disposition of infringing products imported or purchased, or for which a binding commitment to import or purchase was made, prior to the time when the infringer was given notice of the infringement, under such terms as the court deems equitable, taking into consideration the good faith and reasonable business practices demonstrated by the infringer and the need to restore the exclusive rights of the process patent owner. This Act shall not deprive a patent owner of any other remedies available under section 271 of title 35, United States Code, section 1337 of title 19, United States Code, and section 1337a of title 19, United States Code, or any other statutory provision.".

SEC. 3. This Act shall apply only to products sold in the United States or imported after the date of enactment.

SEC. 4. For five years after the date of enactment, the Department of Commerce shall report annually to Congress on the effect of this Act on the importation of ingredients to be used for manufacturing products in the United States in those domestic industries that submit formal complaints to the Department alleging that their legitimate sources of supply have been adversely affected.

SEC. 5. (a) Chapter 29 of title 35, United States Code, is amended by adding at the end thereof the following:

**"§ 295. Presumption: Product produced by patented process**

"In actions alleging infringement of a process patent based on sale in the United States or importation into the United States of a product produced by the patented process, if the Court finds (1) by weighing the evidence that, on balance, there exists a high degree of probability that the product was produced by the patented process and (2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable to do so, then the product shall be presumed to be so produced, and the burden of establishing that the product was not produced by the process shall be on the party asserting that it was not so produced.".

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II

100TH CONGRESS
1ST SESSION

# S. 635

To amend title 35, United States Code, to protect intellectual property rights, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

MARCH 3, 1987

Mr. THURMOND (for himself and Mr. COCHRAN) (by request) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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# A BILL

To amend title 35, United States Code, to protect intellectual property rights, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

## TITLE I—OMNIBUS INTELLECTUAL PROPERTY RIGHTS IMPROVEMENT ACT OF 1987

SEC. 101. This title may be cited as the "Omnibus Intellectual Property Rights Improvement Act of 1987".

### Subtitle A—Intellectual Property Reform Act of 1987

SEC. 111. This subtitle may be cited as the "Intellectual Property Reform Act of 1987".

(3) the term "mask work" has the meaning given it in section 901(a)(2) of title 17, United States Code.

(d) APPLICATION OF SECTION.—This section shall not apply with respect to suits commenced under the antitrust laws before the date of the enactment of this section.

PROCESS PATENTS

SEC. 113. (a) Section 154 of title 35, United States Code (35 U.S.C. 154), is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling products produced thereby throughout, or importing products produced thereby into, the United States,".

(b) Section 271 of title 35, United States Code (35 U.S.C. 271), is amended by—

(1) redesignating subsection (a) as paragraph (a)(1); and

(2) inserting the following new paragraph (2):

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor, a product produced by such process, infringes the patent. A product produced by a patented process will, for purposes of this title, not be considered to be so produced after it is materially changed by a subsequent process, or it becomes a minor or nonessential component of another product.".

(c) Section 287 of title 35, United States Code (35 U.S.C. 287), is amended by—

(1) designating the existing language as subsection (a); and

(2) adding the following new subsection (b):

"(b) No damages shall be recovered by the patentee for infringement under section 271(a)(2) of this title from an infringer who did not use the patented process except on proof that such infringer knew or was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such knowledge or notice. Filing of an action for infringement shall constitute such notice.".

(d)(1) Title 35, United States Code, is amended by adding the following new section 295:

**"§ 295. Presumption: Product produced by patented process**

"In actions alleging infringement of a process patent based on use, sale, or importation of a product produced by the patented process, if the court finds (1) that a substantial likelihood exists that the product was produced by the patented process and (2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so produced, and the

burden of establishing that the product was not produced by the patented process shall be on the party asserting that it was not so produced.".

(2) The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: Product produced by patented process.".

PATENT TERM RESTORATION FOR CERTAIN AGRICULTURAL AND CHEMICAL PRODUCTS

SEC. 114. (a) Title 35, United States Code, is amended by adding the following new section immediately after section 157:

**"§ 158. Restoration of patent term for certain agricultural and chemical products**

"(a)(1) The term of a patent which claims a product subject to a regulatory review period or a method for using such a product or a method for manufacturing such a product shall be extended, in accordance with this section, from the original expiration date of the patent if—

"(A) the product sponsor notifies the Commissioner in compliance with the provisions of subsection (b)(1);

"(B) the product has been subject to a regulatory review period before its commercial marketing or use;

"(C) the term of the patent has never been extended under this section; and

Senator DECONCINI. Senator Lautenberg, we are very pleased to have you here, and I do want to reiterate my thanks to you and your staff for your willingness to consider the differences of our bills that are before us and to constructively work for some solution. I think we can find some common ground here that can achieve what you want to as well as what I and other members would like to achieve, and I am very pleased to have you here today.

## STATEMENT OF HON. FRANK LAUTENBERG, A U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator LAUTENBERG. Thank you, Mr. Chairman and ranking Republican member and members of the committee. I want to commend you for moving promptly on this process patent legislation.

You have introduced a bill that represents a thoughtful approach. As you know, I have taken a different tack on some points in my bill, S. 573. It is my hope that by airing the issues today, we can come closer to reaching a consensus and achieving our ultimate goal, which is the passage of meaningful process patent law.

We are all concerned about America's competitiveness in world markets. By enhancing process patent protection, we can protect American technology and spur investment in innovation. In that way, we can help America compete.

To win the race for innovation, and to enjoy the fruits of victory, we need to protect intellectual property like patents. If we do not, others will be free to steal an invention. They will be free of the risks of research and the frustrating failures that precede success, but they are going to be free to reap the harvest that another inventor sows.

We need to close a major gap in the law dealing with the patents of processes. Current law bars the unauthorized manufacture, use or sale of a patent in the United States. Where a product patent is at stake, and the product is copied abroad, infringement occurs when the product is actually used or sold in the United States. Where a process is at stake, and the United States process is copied abroad, there is no infringement of the process patent, even if the product made by the process is sold or used in the United States.

So our current patent law does not reach the foreign pirating of our most innovative processes even when the products are shipped back to the United States. The Process Patent Act would change that. It would make it a violation of U.S. patent law to import a product into the United States, or sell a product in the United States, if that product was made overseas without permission to use a U.S.-patented process.

While U.S. courts may not reach a foreign manufacturer that has no presence in the United States, the bill would allow a patent owner to enforce its patent in the U.S. courts against the importer or seller of the foreign manufacturer's product.

Japan, Britain, West Germany, and France already make it an infringement of process patents to import products made outside their boundaries through the unauthorized use of a patented process. This legislation would bring American law into line.

Mr. Chairman, my State is one of the Nation's centers for research and development. Billions of dollars are spent each year in the development of patented products and processes. An executive at a major pharmaceutical firm recently wrote me that it costs over $150 million to bring a new product to market.

Especially in the area of biotechnology, the principal form of patent protection can be process protection. According to one study, over half the patents issued in genetic engineering between 1963 and 1984 were process patents.

Process patent protection is important to the businesses that make the investments, and it is important to the people they employ. That is why both business and labor have called for process patent reform.

Under my bill, an importer or seller of a product made through authorized use of a patented process would be liable as an infringer. The importer or seller would be liable for damages only after notice of the infringement. However, the bill requires the patent owner to set forth in its notice its reasons for belief that there has been an infringement.

Also, the bill permits a court, where it deems it equitable, to allow the infringer to continue to sell infringing products. The products must be imported or purchased, or there must be a binding commitment to import or purchase, before notice of infringement is given.

Sometimes it is very difficult to establish in fact that a particular process was used in the manufacture of a particular product. Where there is a high degree of probability that a process was used, and where a claimant has made every reasonable effort to determine that a process was in fact used, the bill would allow a court to shift to the importer or to the first seller the burden of proving that the patented process was not used.

Mr. Chairman, process patent reform is overdue. It was suggested as long ago as 1966 by a President's Commission during the Johnson administration. It was suggested by the Young Commission on Competitiveness.

As the chairman knows, while there is broad support for the principle of expanded process patent rights, there have been disagreements on how to accomplish that. Concerns have been expressed on behalf of importers who may in good faith be unable to determine whether their suppliers are infringing.

I recognize those concerns. There are different ways of addressing them. I have some reservations about the chairman's approach. I have set those out previously. On the other hand, I would concede that my approach is not necessarily the only alternative.

The point I would like to emphasize today is that I believe our differences are easily reconcilable. I know my staff has been working closely with yours and with representatives of interested groups. We can and we must resolve outstanding issues and move on. America's innovators, America's patent owners, America's competitive future cannot wait. I am committed to work with the subcommittee to move forward.

Mr. Chairman, the Industrial Biotechnology Association has several members in my State. I understand there was not time to ac-

commodate their appearance here today, but I would appreciate it if their testimony could be printed in the hearing record.

Senator DECONCINI. Senator, I regret that we could not accommodate everybody, but let me assure you that the record will be open for any statements that will be entered within the next week.

[The following statement was submitted for the record:]

STATEMENT

OF

RICHARD D. GODOWN,

PRESIDENT,

INDUSTRIAL BIOTECHNOLOGY ASSOCIATION

This statement is submitted on behalf of the members of the Industrial Biotechnology Association and concerns the need for reform of our Nation's laws governing process patents. We commend Subcommittee Chairman DeConcini for recognizing the importance of this issue and demonstrating leadership on this issue so quickly. Our industry is grateful for your prompt attention to the process patent problem.

The Biotechnology Industry

It is important to note at the outset that biotechnology is not a product, but rather a group of processes that have in common the use of genetically-altered living organisms to produce products. In ancient times, man used microorganisms to produce bread, wine, beer, and cheese. Today, biotechnology techniques are used to develop new medical, agricultural, chemical, energy, and waste clean-up products that will enhance our future, and our children's future.

Biotechnology was invented in America. Fueled by billions of research dollars, the investment in American biotechnology is

beginning to pay off. In the health care field, recombinant human insulin is available to replace the pig and cow insulin used by most diabetics but to which some are allergic. Among other biotechnology health care products now available is a proven cure for a rare form of leukemia, a vaccine for hepatitis type-B, and a drug that prevents kidney rejection in transplant patients. Biotechnology led to the isolation of the AIDS virus and to the development of the AIDS diagnostic products now used by doctors. Research into an AIDS vaccine is progressing at several biotechnology companies. In 1987, FDA approval is expected for the first block-buster biotechnology product, a naturally-derived protein that dissolves the arterial blood clots that cause heart attacks.

Every one of these important new products was developed by the domestic biotechnology industry that began its existence only fifteen years ago, and now includes an estimated 400 U.S. firms. This includes 300 new firms that were founded specifically to develop the new life science technologies that were pioneered in the early 1970's, including genetic engineering technology, monoclonal antibody technology, and cell culture technology. The domestic biotechnology industry has grown from 1981 revenues of zero to 1986 revenues of $400-600 million with double that anticipated for 1987. The industry has already created thousands of new, high-paying jobs, with additional jobs being created every day.

Clearly, biotechnology is America's future. New health care products are just the beginning. Within the next five years, new biotechnology products will begin to revolutionize American

agriculture, producing plants that can withstand drought, frost, or brackish water; microorganisms that produce organic, biodegradable pesticides; leaner and healthier pork from low-body-fat pigs; and many other products that will increase the quality of American foods and the environment, while decreasing the farmer's cost of production.

It's plain to see why everyone is so excited about biotechnology and so proud of America's leadership role.

But the future of biotechnology will not be as glorious as its past without a change in the process patent law. Indeed, the future of our industry depends more on what Congress does to protect U.S. process patents from unfair foreign competition than from any other Act of Congress likely to occur this year.

Biotechnology Needs Process Patent Reform

America's foreign competitors, most of whom have invested comparatively little in biotechnology research, have targeted our industry for major and concerted competition. In Japan, the Ministry of International Trade & Industry (MITI) and the Japanese biotechnology industry have joined forces and established a central plan to turn Japanese biotechnology into a 127 trillion yen per year industry by the year 2000, almost 11 percent of that country's projected gross national product. We are concerned that the current lack of process patent protection in the U.S. may contribute to the fulfillment of that projection. In Europe, the Concertation Unit for Biotechnology in Europe

(CUBE) coordinates European Community activities from Brussels, and several European countries have established joint research ventures with other countries so as to better compete with the U.S. and Japan. Even the Soviet Union and China have increased their attention to and funding of biotechnology. In fact, China and Japan recently signed an agreement to exchange genetic engineering technology being developed in agriculture.

The U.S. biotechnology industry does not fear fair competition. We have already shown where a combination of American ingenuity, commitment to research excellence, and free enterprise can lead.

But we do fear unfair competition, especially in the form of intellectual piracy. As noted by the congressional Office of Technology Assessment in its 1984 report, Commercial Biotechnology: An International Analysis, continued U.S. preeminence in biotechnology depends in large part on how well the law of intellectual property allows inventors, private companies and others to protect the results of their research efforts from foreign piracy and unfair competition. Without the ability to prevent other companies from taking the results of this effort, many new and economically risky projects that could lead to important new products would not be undertaken.

The emerging biotechnology industry is especially vulnerable to harm because often the only protection available is a process patent. For example, recombinant human insulin is unpatentable; the new biotechnology process for producing human insulin is patentable. Since biotechnology processes are often the only

economically viable methods of producing important new products, as is the case for human insulin, the very availability of these products (and associated jobs) is threatened when a company cannot be assured that its multi-million dollar research program will not be vulnerable to unfair practices by foreign companies.

Congressional Action Needed

Congress must act now to ensure the continued preeminence of American biotechnology. IBA urges the Subcommittee to enact strong process patent legislation, such as is contained in S. 573, Senator Lautenberg's bill, or S. 539, the Administration's bill. We also urge you to resist the temptation to enact bills, such as S. 568, that appear to address the process patent problem but which in fact place unreasonable burdens on research-based companies while being practically unenforceable against known infringers.

The problems with S. 568 result from three interrelated provisions, one creating a compulsory license, one creating a "request for disclosure" mechanism, and one addressing notice of infringement requirements. The bill permits a generic manufacturer to direct a "request for disclosure" to a party engaged in the manufacture of a product. The recipient must then identify all process patents owned by or licensed to that party for the production of the product. If a process patent is disclosed which is thereafter infringed by the requester, there is a six month compulsory license following notice of infringement during which no injunction will lie and only

reasonable royalties may be recovered. If the relevant process patent is not disclosed, the compulsory license period runs 18 months. In either case, effective notice of infringement requires a showing that there is a "substantial likelihood" of infringement. The time period for the six or 18 month limitation on damages does not begin to run until this showing is made.

This causes the following problems for research-based companies:

- o Companies are required to prove their cases, before trial and without the benefit of pre-trial discovery, just to serve effective notice on an infringer. S. 568 requires that a notice of infringement specify facts which are sufficient to establish that there is a "substantial likelihood of infringement." Until this high evidentiary requirement is met, infringement can contiue unabated and without penalty. As a practical matter, this single provision makes the bill unenforceable under most circumstances.

- o The "substantial likelihood of infringement" requirement for effective notice is unnecessary to protect the generic pharmaceutical industry from frivolous suits, as they contend. Penalties under Rule 11 of the Federal Rules of Civil Procedure provide an adequate disincentive for nuisance suits.

- o The recipient of a "request for disclosure" must disclose not only the process patents he owns, but also those he licenses. This latter category often contains confidential business

information to which his competitors would not otherwise have access.

- It is unreasonably burdensome to ask research companies to comply with "requests for disclosure," which are no more or less than requests for free patent searches. In fact, since they will probably do their own patent searches anyway to avoid liability for process patents held by companies that were not recipients of disclosure requests, the disclosure provision operates primarily as a burden on the research company rather than as a benefit to a generic.

- The six month "limitation on remedies" can be fairly characterized as a compulsory license, denying the patent-holder his basic right to prevent others from using his invention without his permission. Not only is this unfair to the company that developed the invention but it would create mischief for our Government's efforts to improve patent protection abroad.

- A research company's inadvertant failure to list a patent can result in an 18 month compulsory license. This is an unreasonable punishment for an inadvertent failure by the non-infringing party.

- The Patent Office, U.S. Trade Representative's Office, and Department of Commerce all opposed S. 568 last year and are likely to continue to do so.

In summary, then, S. 568 is an inadequate remedy for a serious problem.

IBA believes that S. 573 offers a more viable approach. It does not require a research company to perform its competitors' patent searches, it does not authorize a compulsory license, and it does not require a company to prove its case before serving notice of infringement. At the same time, the bill offers considerable protection to innocent infringers. Innocent infringers avoid liability prior to knowledge or notice of infringement; and notice must be supported by evidence, not mere speculation. Furthermore, once notice is served, S. 573 permits companies that have entered into "binding commitments" prior to notice to seek an equitable disposition of the infringing goods received after notice. This provides sufficient protection for innocent infringers without seriously compromising the rights of the patent holder.

IBA urges the Subcommittee to report favorably upon S. 573.

Conclusion

The processes of biotechnology can -- and must -- become a new source of economic vitality for America. There is no question that the agricultural, health, and chemical products of biotechnology have the potential to improve the quality of our lives, and the lives of people the world over, to a remarkable degree. There is also no question that this country has the scientific, manufacturing, and marketing resources to

maintain its current leadership in biotechnology, and to derive significant economic benefits from that position.

But while these things were also true for the electronics industry, the government's failure to take prompt action against unfair trade practices in that industry resulted in a considerable loss of market share to foreign competitors using unfair tactics. This could happen to the biotechnology industry as well, if process patent reform is not quickly undertaken. It could be that, without the safeguards contained in S. 573 or S. 539, biotechnology products may soon come to need a label that says "Invented in America, Made in Japan."

Senator LAUTENBERG. Thank you, Mr. Chairman. I appreciate the opportunity to appear before you.

Senator DECONCINI. Thank you, Senator Lautenberg.

I think we are off to a good start. I have no questions. I know you have a number of constituents in your State, as I do—some of the same ones, as a matter of fact—that are very interested in this issue. You have been a leader in it long before I was because, I think, in your private-sector life, you dealt with this area, and we respect your judgment very much.

Does the Senator from Utah have any questions?

Senator HATCH. No. I appreciate your coming, Senator.

Senator LAUTENBERG. Thank you.

Senator HATCH. I appreciate your efforts in this regard, and I think we are going to work well together to try to effectuate a resolution of this bill.

Senator LAUTENBERG. Thank you.

Senator DECONCINI. Does the Senator from Iowa have any questions?

Senator GRASSLEY. I have no questions.

Senator DECONCINI. We will send you a raft of written questions that you can answer this evening at home. [Laughter.]

Senator LAUTENBERG. Thank you, and I will, of course, Mr. Chairman, reluctantly answer. [Laughter.]

Senator DECONCINI. Thank you, Senator Lautenberg.

Next we are going to have the Commissioner of the U.S. Patent and Trade Office, Donald Quigg.

Mr. Commissioner, thank you for joining us today. If you will summarize your statement, we will put the full statement in the record.

**STATEMENT OF HON. DONALD J. QUIGG, ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS, U.S. PATENT AND TRADEMARK OFFICE**

Mr. QUIGG. Thank you, Mr. Chairman and members of the subcommittee.

I welcome this opportunity to testify on the subject of process patent legislation which would extend the exclusive rights of the holder of a process patent to products made by the patented process.

Process patents have become increasingly important in high-technology areas. However, lack of protection for the products of patented processes severely undercuts their value. Accordingly, in section 113 of S. 635, the administration has proposed an amendment to title 35, United States Code, that would significantly improve the patent law affecting process patents.

S. 635, section 113, would amend the patent law to make domestic use or sale or importation into the United States of a product produced by a patented process an infringement. This section would protect innocent importers, users, or subsequent sellers of an infringing article by providing that no damages would lie against them except on proof that they knew or were notified of the infringement.

This bill would also establish a rebuttable presumption that a product that could have been made using the patented process was in fact so made. These amendments to the patent law would provide the level of protection needed by our research-intensive industries to support their search for newer and better products and to protect them against those who merely copy.

In this light, we also support the principle underlying S. 573. That bill differs from S. 635 in several aspects. S. 573 would statutorily recite requirements for what may be considered "notice" to the infringer and would give advice to courts on how to dispose of infringing products.

We do not favor such enunciations because it would set statutory requirements for the enforcement of process patents apart from those of other patents. This may have the tendency of turning process patents into second-class patents. Despite our preferences, we consider S. 573 to be a good bill that would go far to improve the protection for owners of process patents which is so necessary to enhance America's trade and competitive position.

Regrettably, the same cannot be said about S. 568. Although the underlying purpose of S. 568 is to provide increased protection for process patent owners, it offers that protection at a cost of introducing unacceptable concepts.

First, S. 568 would provide that notice to an infringer contain much more information than is now required in patent infringement cases. In short, the patent owner would be obligated to prove his case before litigation ever began. The bill tilts the playing field against the patent owner even further by stripping him of any remedy for a period of 18 months against infringers who sell to the public and who have been notified of their transgressions.

This practice has been called by its proponents a temporary limitation on damages or a temporary grace period. However, the

result of this limitation is that the patentee is barred from taking action while someone else sells his patented invention. This concept impinges on a patentee's exclusive right and is more appropriately termed compulsory licensing. It has no place in our patent law. In this instance, the 18-month compulsory licenses granted to retailers would even be free of any reasonable royalties.

Other provisions in S. 568 would reduce the patent owner's right to a forced sale of his invention for either 6 or 18 months for a reasonable royalty.

S. 568 would also have adverse international implications. At present, our Government is actively engaged in a major effort to strengthen the protection of U.S.-owned intellectual property in other countries. The administration, therefore, cannot embrace a concept that we have urged other countries to abandon.

Our fundamental opposition to compulsory licenses must not be compromised in the guise of improved patent protection.

Thank you, Mr. Chairman.

[Statement of Mr. Quigg follows:]

STATEMENT OF
DONALD J. QUIGG
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS

ON
S.635, TITLE I, SECTION 113, "PROCESS PATENTS";
S.573, THE "PROCESS PATENT ACT OF 1987"; AND
S.568, "PROCESS PATENT AMENDMENTS ACT OF 1987"

SUMMARY

S.635
Section 113 of this bill would amend the patent law to make domestic use or sale, or importation into the U.S., of a product produced by a patented process an infringement. This section would protect innocent importers, users, or subsequent sellers of an infringing article by providing that no damages would lie against them except on proof that they knew or were notified of the infringement. This bill would also establish a rebuttable presumption that a product that could have been made using the patented process was in fact so made. This addresses the great difficulties a patentee may have in proving his allegation in those cases where the manufacturer is not subject to discovery under the Federal Rules of Civil Procedure. These amendments to the patent law would provide the level of protection needed by our research intensive industries to protect them against those who merely copy.

S.573
We also support the principle underlying S.573. That bill differs from S.635 in several aspects. S.573 would statutorily enumerate requirements for what may be considered "notice" to the infringer and would give advice to courts on how to dispose of infringing products. We do not favor such enunciations, because it would set statutory requirements for the enforcement of process patents apart from those for other patents. This may turn process patents into second class patents. Despite our preferences, we consider S.573 to be a good bill that would go far to improve the protection for owners of process patents.

S.568
Although the underlying purpose of that bill is to provide increased protection for process patent owners, it offers that protection at the cost of introducing unacceptable concepts. First, S.568 would provide that notice to an infringer contain much more information than is now required in patent infringement cases. In short, the patent owner would be obliged to prove his case before litigation ever began. The bill tilts the playing field against the patent owner even further by stripping him of any remedy for a period of eighteen months against infringers who sell to the public and who have been notified of their transgression. This concept is termed a "compulsory license" and has no place in our patent law. Other provisions would reduce the patent owner's rights to a forced sale of his invention for either six or eighteen months, for a "reasonable royalty." The damage caused to our patent laws by introducing compulsory licensing far outweighs the benefits which this bill would provide. Independent inventors and small businesses would espe-

cially be harmed. The bill would also have adverse international implications. At present, our Government is actively engaged in a major effort to strengthen the protection of U.S. owned intellectual property in other countries. The United States, therefore, cannot embrace a concept that we have urged other countries to abandon. Regrettably, we would sooner have no protection for products made by patented processes than accept such protection together with the limitations imposed by S.568.

* * *

Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to testify on the subject of process patent legislation which would extend the exclusive rights of the holder of a process patent to products made by the patented process. Unlike the laws of our major trading partners, U.S. patent law does not give the holder of a process patent the right to stop the importation into, or the use or sale within, the United States of a product made by a process patented in the United States.

Process patents have become increasingly important in high technology areas. However, importation into, and use or sale in the United States of products produced by processes patented in this country are severely undercutting the value of such patents. As a consequence, this practice must be effectively countered by changes in the patent laws to protect the legitimate interests of U.S. inventors.

Under present law, a patent is infringed only if the patented invention is made, used, or sold in the United States. Making, using, or selling the invention outside the United States does not constitute infringement, nor does the mere importation of the invention. Where the patented invention is a product or tangible article, a foreign competitor cannot avoid liability to the patent holder by manufacturing the product overseas and importing it for use or sale in the United States market.

Where the patent claims only a process or method, however, only the use of the process in the United States constitutes infringement. Use of the process outside the United States will not infringe the U.S. patent, nor will use or sale of products made by the patented process. Thus, a U.S. manufacturer who uses the patented process would infringe, while a foreign manufacturer would not. When the chief commercial value of the process comes from the use or sale of the resulting product, sale of the

foreign-made products may effectively destroy the value of the U.S. process patent and the patent holder's ability to recover his initial investment in research and development.

A patentee has two options to protect his patented process. On the one hand, he might seek to obtain patents in as many other countries as possible. This option, however, is unrealistically expensive and largely ineffective because of the impossibility of obtaining adequate protection in all of the countries in which a process might be used. In many important technical fields, such as agricultural chemicals and pharmaceuticals, a number of countries still offer no patent protection. This consideration is particularly important for small and medium-sized businesses which are not doing business abroad and are thus unlikely to seek patent protection in foreign markets.

The other option is to seek relief from the International Trade Commission (ITC) for violation of section 337a of the Tariff Act of 1930, as amended. The patentee can seek a cease and desist order against a particular firm, or an exclusion order that would embargo the importation of products made by the patented process, if the Commission finds violation of the statute. This remedy, however, is not always adequate. The most important shortcoming is that the Commission cannot award damages to a patentee who, therefore, is not compensated for past injuries. Also, although the Administration is seeking its deletion, under present law the patentee must show that such importation has the effect or tendency to destroy or substantially injure an efficiently and economically operated U.S. industry, to prevent the establishment of such an industry, or to restrain trade and commerce in the United States.

Nevertheless, cease and desist orders against particular firms may not be effective where importation of offending products can easily find alternative channels. Also, enforcement of exclusion orders by customs officials can be difficult because of the problem of differentiating products made by the patented process from those that were not so produced.

Although ITC proceedings are an important adjunct to enforcement of patent rights, they should not be the sole remedy available to process patent owners against competition from offshore manufacturers. Accordingly, in Section 113 of S.635, the Administration has proposed an amendment to title 35, United States Code, that would significantly improve the patent law affecting process patents.

S.635

Section 113 of this bill would complement section 337a of the Tariff Act, by amending the patent laws to make domestic use or sale, or importation into the U.S., of a product produced by a patented process an infringement and subject to the full remedies provided by the patent laws. However, a product produced by a patented process would not infringe the patent if the product was materially changed by a subsequent process or if it became a minor or nonessential component of another product. This modification is intended to ensure that products produced by the patented process are protected without unduly prejudicing commerce in derivative products in which the process patent has played an insignificant role.

This section would also protect innocent importers, users, or subsequent sellers of an infringing article by providing that no damages would lie against them except on proof that they knew or were notified of the infringement. Naturally, the filing of an action for infringement constitutes requisite notice. By prohibiting damages for infringing activities which occurred before the infringer had knowledge or notice of infringement, an appropriate balance would be struck between protecting the rights of process patentees and those who innocently use or trade in products produced by the patented process.

Section 113 of S.635 would also establish a rebuttable presumption that a product that could have been made using the patented process was in fact so made. This presumption addresses the great difficulties a patentee may have in proving that the patented process was actually used in the manufacture of the product in question in those cases where the manufacturer is not subject to discovery under the Federal Rules of Civil Procedure. Shifting the presumption should create no substantial burden, as an accused infringer is in a much better position to establish that the product was made by another method.

The rebuttable presumption of manufacture by a patented process should not be casually established, however. To minimize the risk of harassing litigation intended, for instance, to discourage firms from carrying competing products, the presumption would only be available if the patentee demonstrates, on the basis of available evidence, that a "substantial likelihood" exists that the product was made by the patented process. The patentee would also be required to show that despite a reasonable effort, he was

unable to determine what process was used in the manufacture of the product in question. Thus, patentees would have to make initial, good faith efforts to prove these elements in their infringement cases. Placing this burden on patentees should help eliminate frivolous suits.

The amendments to the patent law contained in S.635 would provide the level of protection needed by our research intensive industries to support their search for newer and better products and to protect them against those who merely copy.

S.573

In this light, we also support the principle underlying S.573. That bill differs from S.635 in several minor aspects. It would not exempt from infringement products that have become minor or nonessential components of another product. That exemption, contained in the Administration's bill, may be important to importers of technically complex products. For example, a lag bolt made by a patented process that is used for fastening the seats to the floor of a car should not trigger infringement liability by the car importer.

S.573 would statutorily recite requirements for what may be considered "notice" to the infringer. The patent owner, would have to follow strict criteria, such as giving a description of the patented process claimed and citing the reasons for his belief that such process was used in the production of the product in question. We do not favor such an enunciation, because it would set statutory requirements for the enforcement of process patents apart from those for other patents. This would have the tendency of turning process patents into second class patents, requiring possibly different and more rigorous action on the part of the patentee before enforcement of the patent right could commence. Moreover, faced with the possibility of being assessed attorney's fees for making a frivolous claim, a patent owner will not initiate litigation without first thoroughly investigating the merits of his case.

We also see a problem with this bill's advice to courts on how to dispose of infringing products. In our opinion, products infringing a process patent should not be treated differently from those infringing a product patent. Further, while we strongly favor reversing the burden of proof on the defendant to show that the product in question was not made by the patented process, it may

be prudent to raise the level from a "high degree of probability" to a "substantial likelihood" that the product was produced by the patented process, before establishing such a presumption. This would ensure that unfair burdens are not placed on importers and distributors of noninfringing products.

Despite our preferences in the areas I have enumerated, we consider S.573 to be a good bill that would go far to improve the protection for owners of process patents, that is so necessary to enhance America's trade and competitive position. Regrettably, the same cannot be said about S.568.

S.568

Although the underlying purpose of that bill is to provide increased protection for process patent owners, it offers that protection at the cost of introducing concepts that have no place in our patent laws. First, S.568 would provide that notice to an infringer contain much more information than is now required in patent infringement cases. Before any remedy could be claimed from the infringer, the patent owner's notice would have to set forth facts which are sufficient to establish a "substantial likelihood" that a suspected product was made by the patented process. In short, the patent owner would be obliged to prove his case before litigation ever began. And the clever infringer could turn the issue before the court from a question of infringement into a question of whether he was given adequate notice.

Moreover, S.568 tilts the playing field against the patent owner even further. Specifically, proposed section 287(b)(3) of title 35 would authorize deliberate and informed patent infringement without any available remedy to the patentee. This provision would strip patent owners of any remedy for a period of eighteen months against infringers who sell to the public and who have been notified of their transgression. For eighteen months, the patent would be unenforceable -- which is the same as though the patentee had been forced to consent to the sale or use of his patented invention by others.

This practice has been called by its proponents a "temporary limitation on damages" or a "temporary grace period." However, the result of this limitation is that the patentee is barred from taking action while someone else sells his patented invention. This concept impinges on the patentee's exclusive right and is more appropriately termed a "compulsory license." It has

no place in our patent law. Compulsory licenses are not limited to doing business without permission from the patent owner in perpetuity. Whenever a constraint is placed on the limited exclusivity granted to a patentee, for however short a time span, a compulsory license is created.

In this instance, the eighteen-month compulsory license granted to retailers would even be free of any reasonable royalties. And to make things worse, the eighteen-month period would not begin to run until the patentee actually discovered the unauthorized activities and gave the infringer legal notice of infringement. Prior to detection, the infringer would be free to act with impunity.

Proposed subsections 287(b)(4) and (5) would establish a small refinement of the compulsory license concept. Under these provisions, the patent owner's rights would be reduced to a forced sale of his invention for either six or eighteen months, for a "reasonable royalty." As before, these time periods would not even begin until the patentee discovered the infringement and notified the infringer.

The patentee may be freed from the compulsory license after six months only if he responded to a request for disclosure from a potential infringer and stated which of his process patents might be infringed if the product in question were imported into, or sold or used in the United States without authorization. Failure to respond to such a request, or even an error in responding, lengthens the time of the forced sale from six to eighteen months. Such a procedure runs counter to the traditional relationship between a patentee and the public at large. At present, a person has the obligation to inform himself of those patents which would be infringed if he engaged in a certain activity. In contrast, the proposed procedure would oblige the patentee to conduct patent infringement searches for the potential infringer.

These are our main concerns with S.568. The proponents of that bill have maintained that innocent retailers, such as corner drug stores, would be adversely affected if relief in the form of a royalty-free compulsory license was not provided. We believe this concern is unfounded. Present costs of litigation are so high that it would be economically foolish to proceed against a corner drugstore. We do not see such suits today where product patents are involved. On the other hand, should a massive retail

chain be able to escape liability for infringement, especially where it involves an independent, small inventor? I think not.

Other concerns have been expressed by generic pharmaceutical manufacturers, for example, to the effect that their sources of supplies of active ingredients might be adversely affected by a bill without substantial exceptions to the U.S. patent owner's rights. We believe this concern is also misplaced. A custom chemical industry exists right in the United States with all the technical capability needed to supply this market. And as their manufacturing operations are located in this country, that industry must respect U.S. process patents already -- a constraint which is not now placed on their foreign competitors under our patent law.

In sum, the damage caused to our patent laws by the introduction of the concept of compulsory licensing far outweighs the benefits which this bill would provide. Independent inventors and small businesses would especially be harmed. Often, they do not have the resources to manufacture themselves and, therefore, benefit from their patented inventions only by licensing to others. To the extent that they are unable to grant exclusive licenses because the law would permit other competitors to remain in the market without risk of liability, the value of their patents would be greatly reduced.

In addition, S.568 would have adverse international implications. At present, our Government is actively engaged in a major effort to strengthen the protection of U.S.-owned intellectual property in other countries. This undertaking has been mandated by amendments to the Trade Act of 1984. It is executed by the U.S. Trade Representative, by the Patent and Trademark Office in negotiations under the aegis of the World Intellectual Property Organization, and by the Department of State during the course of many bilateral and multilateral negotiations. Further, one of the major United States initiatives at the GATT meeting of Ministers held in Uruguay in the fall of last year, resulted in the inclusion of intellectual property rights as a subject for discussion in the upcoming round of trade negotiations. It is, therefore, inconceivable that the United States would include compulsory licensing in its patent laws, a concept that we have urged other countries to abandon. Our fundamental opposition to compulsory licenses must not be compromised in the guise of improved patent protection.

Regrettably, therefore, we would prefer to have no protection fo products made by patented processes than accept such protection together with the limitations imposed by S.568. This is not to say, however, that our proposal contained in S.635 is hewn in stone. We would be pleased to work with this Subcommittee to develop process patent legislation that addresses the needs and concerns of all involved.

Senator DECONCINI. Mr. Quigg, thank you very much.

I want to say up front that I appreciate your being here and also your candid observations of S. 568.

Of course, I am very disappointed, as one Member of Congress, that the administration has so far not seen fit to enter into some compromise in this area. I understand your position—more of a purity in the law of process patents—but I cannot help but ask the question, doesn't the administration recognize that we are dealing with issues that require flexibility in our patent laws and that we must balance the interests of the American consumer, such as senior citizens and others, and of the innocent nonmanufacturing purchaser as we add this new form of protection to our laws?

We have seen some very willing parties here who obviously would like to see the law as the administration suggests, "purity" in the protection of patents. But realizing that there are some other interests, and at least in the last Congress, we moved to some successful compromise, and the administration shot it down right at the end. That is your position, and I understand and respect it, though I disagree with it.

But I just want to ask you if you are aware that we need some flexibility here. We are looking for some legislation that will achieve maybe 80 percent of what you want, and I would like your response as to whether or not the administration is really interested in having the full loaf only, only their way, or are they willing to compromise and work with us.

Mr. QUIGG. Mr. Chairman, we certainly are very cognizant of the need to be flexible, and I would say that our bill, S. 635, is not set in concrete. However, I would like to point out that, with S. 568, we might go so far as to say this really protects a foreign manufacturer. How? Well, of course, the U.S. patent owner cannot reach that manufacturer. The only remedy he has is against the purchaser of the goods over here.

Well, if we remove the right of the process patent owner to go against the purchaser or the retail marketer, then this encourages the retail marketer to go to a foreign manufacturer.

Now, let's contrast this with a manufacturer that might infringe the process patent in the United States. There, the process patent owner has a right to go against the manufacturer. He is not going against the retail marketer. He has a right to extract the due for the patent from the manufacturer here.

So what we have done—if we say no, you cannot charge anything for these products that are sold in the 18 months plus the 6 or additional 18 months—we have really deprived the patent owner of

any recovery for the foreign manufacture, but if it is manufactured here in the United States, then the patent owner can recover.

Senator DECONCINI. Well, you raise an interesting issue, and of course, let me say I am not set in concrete in S. 568, either, so we obviously are off to a good start.

Mr. QUIGG. Good.

Senator DECONCINI. We both have agreed that we can even write a new bill, as far as I am concerned. My real objective is to get something here.

You talk about this concern regarding the issue of compulsory license, and that to me was not what we did in last year's bill, but that is where the Secretary came down, I understand. Everyone agrees, I think—and please correct me if you do not agree—that innocent purchasers should not be liable for process patent infringements committed by their suppliers until they receive an adequate notice of infringement. Do you agree with that?

Mr. QUIGG. Yes, indeed.

Senator DECONCINI. And it is obvious that, at the moment when the notice is received, the purchaser will have an inventory of goods and has to have some period of time to do something with them. What are your suggestions in that area?

Mr. QUIGG. My suggestion would be, one, either let the court determine how that is to be disposed of; or, two, let the retailer pay a royalty for that——

Senator DECONCINI. Well, let me interrupt you a minute. Is it the administration's position that Congress should abdicate its responsibility to the court and not attempt to set some time period here? It seems to me we are inviting more litigation and doing exactly what we are always criticized here for not doing, and that is not streamlining our court system if we just say, "Take it to court."

Mr. QUIGG. Well, I think you can handle it simply by saying that the retailer, for sales after the notice, would pay a reasonable royalty. I think that would handle it without going to court.

Senator DECONCINI. Well, let me ask you this. If a retailer knows that he has to pay a royalty, that is going to reflect in the price he charges. If he is really innocent—and let's make that assumption—how do you cover that? He just eats that royalty and doesn't have a chance, or would he have to go back and increase his price and then have customers that bought it at another price awfully upset?

Why can't you suggest some limited period of time where there would not have to be royalties? I am not saying 18 months or 6 months or 12 months or 10 months or anything. But don't you think there is some reasonable period of time, Commissioner?

Mr. QUIGG. Mr. Chairman, I guess maybe my thinking is affected by the fact that we are dealing so much with foreign governments who have compulsory licenses in their laws. We are trying to tell them, Look, this is something the United States does not stand for; we cannot stand for it. We need to get that provision out of your law. But here, if we have a period of time in which we tell the patentee, Look, you cannot enforce your patent against this retailer, we in fact have put compulsory licensing into our law.

Senator DECONCINI. The dilemma you leave me with—and we can leave this to some more negotiations—is that we had a royalty

payment in the bill, and we interpreted your objection to that, that it was similar to compulsory license, so we took it out in our original draft. Are you saying now that you would accept a royalty provision and that it would not be considered a compulsory license?

Mr. QUIGG. Well, it is certainly better than saying that there would be no charge at all. Obviously, with an inventory there, you either have to say no charge for it or you pay something for it. It is a matter of degree, I agree. But rather than tell the retailer you have got to destroy that entire inventory, you have got to find some way of letting him dispose of it.

I think equity would say it is better to have him pay a royalty for that inventory than to have him say, "We don't owe a thing; we will go ahead and market it the way it is."

Senator DECONCINI. Even if he is totally innocent?

Mr. QUIGG. Pardon?

Senator DECONCINI. Even if the retailer is totally innocent and is more than happy in the future not to buy that product but has a contract for at least what is on the shelf?

Mr. QUIGG. Well, Mr. Chairman, this is really no different than if the retailer had purchased a product that was covered by a product patent. Once that notice is given to him, he is subject to the payment of damages.

Senator DECONCINI. You see no difference between a process patent and a product patent? You think they are totally the same?

Mr. QUIGG. I think that they are intellectual property; they should be enforceable; and that, once the notice of infringement has been given, yes, they should be handled in exactly the same way.

Senator DECONCINI. Thank you. I have no further questions. I will submit some for the record.

Senator Hatch?

Senator HATCH. I sure don't agree with that. First of all, your approach would be just as much compulsory license as S. 568, and the reason it would is that yours is open ended, subject only, if we write a royalty provision in there, to a royalty.

Now, we have a royalty provision in S. 568, and we set a limit of time so everybody knows exactly where they are coming from so that we don't allow the courts make all kinds of new rules and unanticipated interpretations. It seems to me the only difference is that we put a period of time in S. 568.

In any case, I do not agree with you that a process patent is exactly the same and should be treated exactly the same as a product patent. But let me just ask a few questions here.

I am puzzled by your criticism of S. 568 for including the "substantial likelihood" standard for the establishment of notice. It was my understanding that, during the 99th Congress, the administration supported Congressman Moorhead's substitute for our substitute for H.R. 4899, which contained the identical language as to the substantial likelihood standard in the notice provision. Isn't that true?

Mr. QUIGG. In the last moments of the Congress, and as an attempt to get something that would be reasonable, the administration said, "We will accept it." We cannot accept anything which contains the compulsory license concept.

Senator HATCH. How does yours differ from ours? We set a time limit. You said no time limit. Now, either way, the person can sell the inventory, and the only difference is that we set a time limit so everybody knows, basically, what they have to live up to, and the courts know, so that we do not have some court setting a time limit arbitrarily. If we provide no standard here I can see the court setting no time limit, or setting a broad time limit, or setting some intermediate time limit. Why don't we establish the appropriate time limitation instead of leaving it to the courts?

That is what is wrong with most legislation up here: we make it all wide open and let the courts decide everything. That is why we have the mess in this country that we have today.

Mr. QUIGG. Well, it seems to me that, in disposing of the inventory, it does have a time limit. It is not spelled out in months or weeks or days——

Senator HATCH. What is wrong with spelling it out? And why does that make it any more a compulsory license than not having a time limit, where you have a compulsory royalty?

Mr. QUIGG. As I said, the matter is a matter of degree. I think that where it is spelled out that a royalty will be paid for the inventory that is in place, that we do not give the concept to the foreign countries that we are departing from a position that we have taken for many, many years.

Senator HATCH. In your statement supporting S. 635 for including the substantial likelihood standard in the section providing for a rebuttable presumption, you note that such a strong standard is required to minimize the risk of harassing litigation intended to discourage firms from carrying competing products.

Now, is it not true that the potential for market intimidation exists at the point of notice as well, given that that notice is the point at which damages begin to accrue?

Mr. QUIGG. I am not certain that I understand your question, but if it has to do with intimidation, yes. Intimidation can take place at almost any point.

Senator HATCH. So it could be at either point.

Each of the proposed bills recognizes the concept that the purchaser of infringing goods is not financially liable for process patent infringement committed by a supplier until he receives adequate notice of such infringement.

Mr. QUIGG. That is right.

Senator HATCH. Now, certainly at the point notice is received, the purchaser will have an inventory of goods on hand. In keeping with the principle that the purchaser should incur no liability prior to notice of infringement, it is necessary to provide, it seems to me, a mechanism for the disposal of his inventory on hand. You have said, well, just provide a royalty.

Mr. QUIGG. Yes.

Senator HATCH. You are critical of the mechanism in S. 568 which provides a limited time period for sale of inventory with reasonable compensation to the patent owner or the royalty, whatever you want to call it. What would be your preferable mechanism for resolving this, just plain leave it open so they can sell whatever inventory off that they have prior to notification, or would it be

better to have a timeframe so that we know? Either way, it seems to me, using your definition, you have a compulsory license.

Mr. QUIGG. I would leave it open for the sale of those goods which he has in actual inventory at that time.

Senator HATCH. So, if they have a 10-year inventory, they can just go ahead and sell it subject to a——

Mr. QUIGG. Well, if they have a 10-year inventory, it is an unusual business, I think.

Senator HATCH. Well, it might become the norm under your rule. Alternatively, it might become the norm, if we set a timeframe, for them to not go beyond that certain timeframe.

Mr. QUIGG. I think it would be very economically unattractive for the retailer to do it.

Senator HATCH. It depends, doesn't it? It depends. There may be some areas where it may be very economically attractive. But, be that as it may, isn't it better to have some sort of time referral that you can refer to than to just leave it open ended, any way you want to?

In S. 568, we have 18 months in which no payment is required.

Mr. QUIGG. Yes.

Senator HATCH. And then we have another 6 months in which a royalty would be paid, or 18 months, depending on whether we are speaking of an importer or a retailer.

Well, let me pursue further the concept of sale of goods that are in inventory or on order prior to the notice of infringement. It has been brought to my attention that the goods for which the purchaser has made a binding commitment to purchase, and have been partially or wholly manufactured, should also be included. Is that right?

Mr. QUIGG. I would limit it to the goods that are actually in place.

Senator HATCH. Do you see any problem with excluding from financial liability not only goods that are in inventory or in transit but also goods for which a binding commitment to purchase has been obtained prior to notice?

Mr. QUIGG. There would probably be some financial liability, yes.

Senator HATCH. All right, thank you.

Thank you, Mr. Chairman.

Senator DECONCINI. The Senator from Iowa?

Senator GRASSLEY. I don't have any questions until the next panel, Mr. Chairman. Thank you.

Senator DECONCINI. Thank you, Mr. Quigg.

We look forward to working with you. We can see that we have a long way to go.

Mr. QUIGG. Thank you.

Senator DECONCINI. I want to call our first panel.

Senator HATCH. Can I make one other comment?

Senator DECONCINI. Yes. I yield to the gentleman from Utah.

Senator HATCH. Mr. Quigg, I have a lot of respect for you, but I really think you had better sit down and talk to us about this because I do not see, really, much difference other than uncertainty in your approach from what we would like to do. But we are flexible. We are willing to resolve it, but, by gosh, I want you to sit down and get it resolved with us.

There is no one way of doing this, but it seems to me that to leave it open ended is just leaving it up to the courts to decide how to solve this, and I think that the court system is the institution least suited for resolving those types of problems.

Mr. QUIGG. Senator, we have sat down and talked.

Senator HATCH. Well, let's talk some more.

Mr. QUIGG. We hold ourselves available any time that it is desired to do that.

Senator HATCH. All right, because we have got to resolve this, and we may very well resolve it the way we want to, but we would like to have your best input.

Mr. QUIGG. Thank you.

Senator DECONCINI. I thank the Senator from Utah. I concur with that.

Our first panel will be Roy Massengill, general patent counsel for Allied-Signal. I want to thank Mr. Massengill for his role in moving this process forward. His company has suffered tremendous losses from this gap in our current patent laws, yet you have continued, Mr. Massengill, to be willing to work toward a solution.

Also, I am going to ask Gerald Mossinghoff, president of the Pharmaceutical Manufacturers Association, to join Mr. Massengill. He is a former Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

Gentlemen, your full statements will appear in the record. Due to the time and two more panels to follow you and having to get out of here by noon, we would ask that you summarize your statements, if you would, and we will put the full statements in the record.

Mr. Massengill?

## STATEMENT OF ROY H. MASSENGILL, GENERAL PATENT COUNSEL, ALLIED-SIGNAL, INC.

Mr. MASSENGILL. Thank you, Mr. Chairman.

I am the general patent counsel of Allied-Signal, which is a multinational company involved in aerospace, automotive, and engineering materials.

At the end of 1986, the company employed approximately 146,000 employees around the world, of which some 18,000 are engineers, scientists, and technicians. We added about 431 U.S. patents to our patent portfolio of more than 33,000 patents worldwide, either issued or pending.

There is widespread agreement that the United States needs protection against those who use our patiented process technology abroad and ship the products into this country. This practice is nothing short of piracy. It steals the technology of the country and it steals our technological future.

This committee has introduced legislation early in the session, for which we commend you. It gives us time to work out, hopefully, a compromise so that we can get this sorely needed legislation enacted. The committee reported legislation in the 98th Congress and the 99th Congress. Both times, time ran out before we had an opportunity to resolve all of the differences and diverse interests of the parties involved who were affected.

I want to commend you, Mr. Chairman, and Senator Hatch and Senator Thurmond, for introducing S. 568 early in the session and scheduling these hearings today.

Allied-Signal has worked for more than 3 years with several parties, trying to work out a compromise to get this legislation enacted. It has not been an easy task. There are many diverse interests, as you will hear today in the testimony.

We thought that we had a reasonable compromise worked out last session. There are lots of provisions that we do not like for industry in this country. There are several provisions, I think, that can be improved, and I think that we ought to work on improving those provisions. We have time in this session, I think, to work on trying to reach some sort of balanced bill that will be acceptable to all of the parties.

I would like to conclude my remarks by saying that we have tried to understand the issues involved. We think we understand how this bill will impact the interests of the parties affected. Our conclusion is that we do not believe it will impact the parties as severely as they think it will. I do not think it will throttle the generic drug industry or the retailers as much as they suspect that it will, nor do I think it is going to have as great a negative impact upon industry that some of our members think it might have.

With regard to the retailers' sales, I think any losses to the patent owner are rather de minimis. There are not very many patent owners who are going to be suing retailers in the first instance.

We are more concerned about the substance of the bill than we are some of the procedural aspects. We want to get at the real infringement. We are more concerned about people altering products and shipping them into this country buried in a value-added product and frustrating the efforts of the patent owner to enforce their patent rights against that kind of infringement than the infringement of some retail store on the corner.

Not only does this practice frustrate the rights of the inventor to enforce his patent, but it also worsens the trade balance by bringing in value-added products. If we are not careful with this legislation, we are going to get too engrossed in procedural things that amount to de minimis harm to the patent owner and probably miss out on really getting a substantive bill to protect the interests that are substantial.

I thank you, Mr. Chairman, for inviting me to appear before this distinguished subcommittee this morning.

[Statement of Mr. Massengill follows:]

Testimony

of

**Roy H. Massengill**

General Patent Counsel

**Allied-Signal Inc.**

Thank you Mr. Chairman:

I am Roy H. Massengill, General Patent Counsel of Allied-Signal Inc. Allied-Signal is a multinational advanced technology company whose businesses are focused in three segments: aerospace, automotive and engineered materials. At the end of 1986, the company had approximately 137,000 employees working in some 800 plants, technical centers, sales offices and other facilities.

Approximately 18,000 Allied-Signal employees in 101 laboratories and technical centers around the world are involved in research, development and engineering. In 1986, RD&E spending totaled approximately $1.3 billion.

Last year, we added 431 patents to the more than 33,000 United States and foreign patents, in force or pending, that we own.

There is widespread agreement that the United States needs protection against those who use its process technology abroad without authorization to make products which are then imported and compete with products manufactured in the United States by the same technology. This practice is nothing short of piracy. It steals the technology this country needs to remain competitive. It steals our technological future.

This Committee reported legislation in the 98th

Congress only to see it die in the final hours of that session. Last year the Senate passed legislation only to see it die in the final hours of the 99th Congress. This historic 100th Congress is working hard to improve the competitive position of the United States. This patent legislation should be part of that program in order to place us on a comparable footing with our trading partners.

I want to commend Chairman DeConcini and Senators Hatch and Thurmond for introducing S.568 early enough in this session so that the frustrations we all experienced in the final days of the 98th and 99th Congresses can be avoided. I also want to thank you, Mr. Chairman, for your early scheduling of this hearing early. The crux of our failure to achieve final passage in past years has been the strong self-interests of various parties which may not be entirely compatible. When the legislation languished until the final days of each Congress, there was not enough time to resolve those differences.

Last year, Allied-Signal was involved, along with many others (including the generic drug industry, numerous Pharmaceutical Manufacturer Association members, fellow industrial companies, retailers, textile manufacturers, and various trade associations) in trying to arrive at a compromise which would address the various represented concerns. That effort was at the urging and under the aegis of many Members of this Committee, and was finally accomplished with the help of Committee and Members' personal staff. The result was a bill which passed the Senate last year and which Chairman DeConcini has re-introduced.

We are pleased that we were able to help develop that

compromise and keep process patent legislation alive, and we are pleased that S. 568 has been introduced to keep this important legislation moving forward. We do, however, acknowledge that the bill had its detractors last year and that even some of its supporters are now backing alternative legislation. Those reactions are to be expected. It was a hard fought compromise. In such situations, no one is ever entirely satisfied.

This is a new session. We are pleased that so many parties are working to move process patent legislation forward. In addition to those sponsoring S.568, we also appreciate the efforts Senator Lautenberg has made. And we are glad to note that the House Judiciary Committee has unanimously reported out H.R.1931, which is the same legislation that the full House passed last year under the bi-partisan leadership of Representatives Moorhead and Kastenmeier. Yet, to date, no one has been able to sufficiently modify last year's compromise to satisfy their own particular interests without antagonizing the self-interests of other impacted parties. However, as more parties work together toward the commmon objective of protecting legitimate intellectual property rights, I am confident that workable legislation can be enacted.

We have supported S. 568, but I am not suggesting that it cannot be improved, and I am certain that neither the Committee nor Allied-Signal are adverse to improvements. However, past experience has shown that parties are much more willing to negotiate and work for improvements when the legislation is moving. When the legislation is moving forward, parties are more inclined to participate rather than remain intransigent.

Mr. Chairman, I urge the Subcommittee to report S. 568 to the full Committee so that we may proceed to make any changes necessary to achieve final passage early this session, not at the end of the session, or the end of the 100th Congress, or in some future Congress.

If I sound impatient, Mr. Chairman, it is because I see foreign competition exploiting research that cost Allied-Signal tens of millions of dollars. I see it happening to other American companies. I appreciate the efforts that former Senator Mathias, that you, that Senators Hatch, Leahy, Thurmond and Lautenberg and your staffs have made to keep our feet to the fire. Those efforts helped forge the bill which was passed last year. We are confident that with your continued leadership, this important aspect of American competitive excellence - process technology - will finally be protected from foreign piracy.

Thank you for the opportunity to appear here today. I would be glad to answer any questions you might have.

Senator DECONCINI. Thank you, Mr. Massengill.

I appreciate your willingness here. You mentioned that we have a lot of time. It depends on whether or not we try to report a bill out of our subcommittee or try to modify it at the full committee. It is my hope that in the next couple of weeks—maybe that is a lot of time—I have not talked with my distinguished colleague from Utah, but I would hope that we could put something together in a meaningful manner in that timeframe.

Mr. Mossinghoff, thank you for being with us, and we appreciate your interest and our discussion yesterday of your willingness to work toward some realistic solution.

Please proceed with your summary.

## STATEMENT OF GERALD J. MOSSINGHOFF, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

Mr. Chairman, it is an honor to appear once again before this distinguished subcommittee.

In the first three pages of my statement, I outline the broad reasons why this legislation is important, but I think you and Senator

Hatch did better in your opening statements than I would do, so let me go to the bottom of page 3 and just say that PMA supports S. 573, the Process Patent Act of 1987, introduced and discussed by Senator Lautenberg.

This legislation would amend the law in a straightforward way to allow U.S. process patent owners to enforce their rights and includes an essential provision to reverse the burden of going forward with the evidence in court proceedings.

In addition, we believe that legitimate concerns of the unknowing infringer are satisfied by a provision in the bill for equitable distribution of infringing products under the court's supervision.

The administration's process patent amendments are contained in S. 635, which has already been disussed. PMA also supports that proposal. In our view, both S. 573 and the administration's bill generally provide the same essential rights to process patent holders. The differences between the two measures are relatively minor and could readily be resolved, we believe.

In some ways, the bill introduced by Senator Lautenberg is a compromise between the administration's bill and your and Senator Hatch's bill in that it does provide opportunity, under broad congressional guidance, to a court of equity to fashion relief for the innocent retailer based on all the circumstances that are present in the case before the court.

We appreciate, certainly, your efforts, Mr. Chairman, and those of Senator Hatch in this area, but we believe that S. 568 would introduce novel and undesirable concepts into U.S. patent law. We share the concerns raised by the administration with respect to the 6- and 18-month provisions for limiting damages, and I think there is a real substance to the Secretary's position in that regard, having had a lot of experience in the World Intellectual Property Organization.

People who would foster the pirating of inventions seize upon anything they can find in the diplomatic negotiations, and we think something that looks like a compulsory license would have some significant impact on the way this country would conduct its negotiations within the World Intellectual Property Organization.

In addition, we object to the complex procedure for disclosure of all process patents upon request. That is an unprecedented, in our opinion, and unnecessary provision. It is an unnecessary and novel burden upon patentees. And we find objectionable the requirement that the patentee may give adequate notice of infringement only if he first sets forth facts establishing a substantial likelihood of infringement.

Mr. Chairman, before I conclude my testimony, I think it would be helpful to the committee to define terms. There has been a lot of discussion about the generic drug industry. The PMA member companies that I am proud to represent—they are the research-based pharmaceutical companies of the United States—in fact produce, depending on how you define terms, between 70 and 80 percent of all generic products sold in the generic drug market. So I can assure the committee that, at least for that 70 or 80 percent of the generic drug industry, represented by the PMA, strongly supports Senator Lautenberg's bill and the administration's bill.

Also, we do not see any need for any special favoring amendments such as this disclosure rule to be applied to protect the small percentage of the nonresearch based generic drug industry. That industry is enormously profitable. It is much more profitable than research-based industries in terms of return on stockholders' equity, which is the economic definition of profit.

That industry, the generic-only industry, is 87 percent higher, more profitable, in 1985, and in terms of return on assets, that industry is about 2½ times as profitable as the research-based industry. We believe that industry is a strong, profitable, healthy industry and is perfectly able to take care of itself under the normal rules of patent disclosure, and that is that these people know what is happening in the industry.

It is not as if one is an innocent manufacturer abroad and that there are 5 million patents that one has to search. The industry intelligence is such that one knows exactly what processes are patented. Those are well reported in the trade literature. And so we would object to that complex disclosure provision that occurs in the bill that was discussed at the last end of the 99th Congress.

Mr. Chairman, that concludes my prepared summary, and I would be pleased to respond to any questions you may have.

[Statement of Mr. Mossinghoff follows:]

PREPARED STATEMENT OF

GERALD J. MOSSINGHOFF
PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Mr. Chairman and Members of the Subcommittee:

I am Gerald J. Mossinghoff, President of the Pharmaceutical Manufacturers Association. PMA is a national trade association representing over 100 pharmaceutical companies who are responsible for the vast majority of new drugs introduced in the United States and virtually all pharmaceutical research and development in this country.

PMA companies rely on the incentives of the U.S. patent system in conducting their research and development activities, and regularly obtain patent protection for the results of their innovative efforts. I appreciate the opportunity to appear before the Subcommittee and testify on the important subject of increased U.S. protection for patented processes.

Process patent legislation will improve our patent laws by eliminating the opportunity for copiers to avoid infringement and effectively obtain free use of U.S. research and development expenditures. Strengthening our process patent law is supported by the Administration and a broad range of companies and industry and patent law associations and is included in bills designed to increase America's competitiveness in international markets. The legislation will eliminate a deficiency in the patent code and bring our law into conformity with the patent laws of other major industrialized trading partners, including West Germany, France, the United Kingdom and Japan. PMA, therefore, strongly supports enactment of legislation making it a violation of our law to import a product into the United States or to use or sell a

product here, if that product is made overseas without authorization using a U.S. patented process.

The bills introduced in Congress would amend the patent code so that a company would not be able to circumvent legitimate patent rights simply by practicing the patented process in a foreign country. Anyone could continue to import an unpatented product which was made by a process not covered by a U.S. patent. Damages would be available for infringement, but only after the patent holder has given adequate notice to parties, and the notified party continues to infringe.

Process patent legislation will generally benefit companies which seek to patent innovative manufacturing processes, including pharmaceutical and chemical companies. A PMA member company recently prevailed in a process patent action before the International Trade Commission under Section 337 of the Tariff Act. The action was filed in January of 1984; a determination followed three years later in late December, 1986. Despite the ITC's finding that "substantial injury" had occurred, the only remedy available through the ITC was an exclusion order administered at the border. No monetary damages are available through the ITC or any other entity for process patent infringements abroad. Had there been the needed provision in our patent code, the company would have been able to stop the infringing action more quickly in the Federal courts and would have been entitled to damages. The legislation would have an immediate and direct impact in the biotechnology area, where product patent protection may not be available.

PMA supports S.573, the Process Patent Act of 1987, introduced by Senator Lautenberg. This legislation would amend our law in a straightforward fashion to allow U.S. process patent owners to enforce their rights, and includes an essential

provision to reverse the burden of going forward with the evidence in court proceedings. In addition, the legitimate concerns of the unknowing infringer are satisfied by a provisio. in the bill for equitable disposition of infringing products under the court's supervision.

The Administration's process patent amendments are included as Subsection 3103 of S.539, the Administration's omnibus trade bill. PMA also supports the Administration's proposal. In our view, both S.573 and the Administration bill generally provide the same essential rights to process patent holders. The differences between the two measures are relatively minor and could readily be resolved by Congress during the legislative process.

While we appreciate your efforts, Mr. Chairman, and those of Senator Hatch in this area, PMA believes that S.568 would introduce novel and undesirable concepts into U.S. patent law. We share the concerns raised by the Administration with respect to the 6 and 18-month provisions for limiting damages, and the mischief such provisions could cause in our Government's efforts to improve patent protection worldwide. In addition, the complex procedure for disclosure of all process patents upon request is unprecedented and unnecessary and would be unduly burdensome for the patentee. And we find objectionable the requirement in S.568 that the patentee may give adequate notice of infringement only if he first sets forth facts establishing a substantial likelihood of infringement.

Mr. Chairman, this concludes my prepared statement. I appreciate this opportunity to appear before the Subcommittee to express PMA's support for S.573 and S.539. And we are grateful for the Subcommittee's resolve to enact much needed remedial legislation regarding process patents.

Senator DECONCINI. Thank you, Mr. Mossinghoff.

Mr. Massengill, Allied-Signal has recently been involved in process patent litigation before the ITC, so I know you have firsthand experience with the current law.

I know legislation has been proposed to change section 337 of the Tariff Act regarding patent actions brought before the ITC. Do you agree that those changes need to be made, and would those changes, if they were enacted, alleviate the need for the proposed process patent amendments to the patent law that we are discussing today?

Mr. MASSENGILL. I certainly support the changes being made. They are needed to improve on section 337 actions. However, even with those changes, a section 337 action will not be an adequate remedy for a patent owner. Process patent legislation will also be needed.

The proposed changes before the ITC would primarily make it easier, less burdensome, for a patent owner to bring an action against an infringer, but it would do nothing with regard to awarding damages and attorneys' fees, or taking care of the problem customs has with regard to, stopping products from coming into the country, even though there is an exclusion order.

Our experience has been that all products are not excluded—and this is no criticism of Customs—it is like the immigration department trying to stop all the illegal aliens coming into this country. When you give the task to the customs department to stop all goods, even with the exclusion order, it is practically impossible for them to stop all of the banned products. Importers will shop from one port of entry to another to get their product in, and once the product gets into this country, there is really nothing you can do about it.

So this legislation is definitely needed.

Senator DECONCINI. Well, Mr. Massengill, thank you. So you think we still need to proceed with this legislation, obviously.

I want to thank you for your remarks and your statement inference that, though certainly retailers should be subject to patent laws and enforcement, our thrust here is to get to the importers and those who are abusing this process, and though retailers get a big benefit out of it, that really has not been where we have been looking. We want to curb this in a meaningful way.

Mr. Mossinghoff, through this legislation, we are creating a new set of patent liabilities based on innocent buyers being responsible for the acts of their suppliers. In many cases, there is more than one process that the supplier could be using to produce a product, and if the purchaser knew which process the patent holder intends to claim as covering the off-patent product, the purchaser can at least attempt to find suppliers who use other processes.

You object today to the disclosure procedure which was suggested in the last Congress as a means of accomplishing this goal. I have not heard of any better suggestions since then. What can you propose to us today?

Mr. MOSSINGHOFF. Mr. Chairman, I think that, in the commercial realm, I agree totally with Mr. Massengill, Roy, that our companies do not go around suing retailers or our suppliers. That is sort of a rule of business that is observed, I think, pretty reliably.

Second, at least when I was in the practice of patent law, we provided our clients with standard indemnity and hold-harmless provisions which were part of the terms on their sale or purchase. That is under the Uniform Commercial Code and under virtually every purchase order I have ever seen. There is an indemnity provision indemnifying retailers against patent infringement. That is one of the things that a retailer——

Senator DECONCINI. Are you suggesting that we might consider putting that into this legislation, mandatory indemnity?

Mr. MOSSINGHOFF. Whether it is in the legislation or not, that is the normal business practice of retailers who purchase things. Normally, their purchase orders contain that provision, and if it is not in there and it is a Uniform Commercial Code State, it would be in there because of the Uniform Commercial Code.

Senator DECONCINI. Are you telling me that all agreements are that way; all foreign manufacturers sign those kinds of agreements? I do not know.

Mr. MOSSINGHOFF. I am not in a position to say all, Mr. Chairman, but I know that that is a normal——

Senator DECONCINI. Would you say most?

Mr. MOSSINGHOFF. Yes. Most purchase orders by retailers to their wholesalers or to their importers contain a patent indemnity provision.

Also, there is a provision—our board of directors specifically and unanimously recommended enactment of the two bills that I have mentioned, the administration's bill and S. 573, which is somewhat of a compromise in itself. But we are aware of the bill that is being considered over in the House of Representatives, H.R. 1931, I believe, and that has a provision in it that states you have to go up to the highest level of source, and so before you can sue a retailer, you have to demonstrate that you could not get to the supplier or the importer of that.

That is another way to perhaps legislatively indicate that we are not to go around suing retailers who innocently have infringed, or are buying products that infringe, process patents.

We believe that the people at the importing level and at the manufacturing level know exactly what they are doing. The trade press and the reports are pretty thorough in documenting what patents and processes have been issued——

Senator DECONCINI. You don't think there are any innocent——

Mr. MOSSINGHOFF. I think you would be very hard-pressed to find one who is truly innocent at the importing level.

Senator DECONCINI. Do you support the House bill that you mentioned?

Mr. MOSSINGHOFF. Our board of directors has not specifically considered it. I would say that I would urge upon the board that we support the House bill, with one change. We think it has a far too strident method of providing notice, that we have to, in effect, prove our case and indicate a substantial likelihood of infringement before you could even have the notice provisions applied. We would recommend that one change.

I cannot speak for the board because they did not consider it, but I would recommend that we would find in that bill some things

that might allay some of your concerns as you have expressed them this morning.

Senator DECONCINI. Are you inalterably imposed to any time period, retailer or supplier?

Mr. MOSSINGHOFF. I think, based again, Mr. Chairman, on my experience during my 4 years as U.S. Representative to the World Intellectual Property Organization, that I think a time period would be seized upon internationally as a statement that says the U.S. Congress has now enacted a compulsory licensing provision, so don't tell us compulsory licensing is not a very good idea.

Now, in the U.N. system, logic does not necessarily prevail over rhetoric, and——

Senator DECONCINI. What if Congress writes into the bill, that this is not a compulsory license, and the intent of Congress is not to create such, and we give a period of 60 days? I just take that off the top of my head. Would you oppose any time period at all?

Mr. MOSSINGHOFF. I would like to say that we would be willing to work with you on it. I think we would have to see it. The board has given me, obviously, the instructions on the two bills that we do support, but we also certainly want to work with you and Senator Hatch and Senator Grassley to try to reach a solution. So I don't want to say we are unalterably opposed to that at this point.

Senator DECONCINI. Thank you. That is encouraging because I am not committed to those time periods, and maybe your suggestion here, looking at that House bill, is a possibility, and we will consider it.

Mr. MOSSINGHOFF. I would say, Mr. Chairman, that I do believe we would be unalterably opposed to that disclosure provision. We think that is a new, novel, and very mischievous provision which we find totally unnecessary to protect legitimate interests.

Senator DECONCINI. The Senator from Utah?

Senator HATCH. Let me start with you, Mr. Massengill.

It has been suggested by some parties interested in the process patent legislation that it is not a critical problem if we fail to achieve a process patent bill this Congress because they expect an international treaty to be negotiated over the next few years that might resolve many of these concerns.

Now, in your view, is it critical for American business that we move ahead this year and pass a process patents bill?

Mr. MASSENGILL. My view, very strongly, is that Congress should pass a bill.

Senator HATCH. All right.

Jerry, in your statement, you note that you share the concerns raised by the administration with respect to the 6- and 18-month provisions for limiting damages. Can I assume by that statement that you are not interested in establishing legislative certainty with respect to the sale of goods on hand or in transit at the time of notice? If you had an approach to that—you have indicated you would like to work with us on it—why don't I just ask you to consider an approach that might help to resolve this dilemma?

Mr. MOSSINGHOFF. All right.

Senator HATCH. Because we need to have more, I think, definitiveness in this bill, and I agree with Senator DeConcini; we can make it clear that this is not intended to establish a compulsory

license and give you the hook to be able to make the arguments overseas that you would like to make.

But I just don't want to leave this up to the discretion of the courts, and I think you can understand that. I think we do far too much of that in the Congress, and especially in this area. It might turn out to be a real mess if we do that; in fact it probably will.

It is not that I don't have confidence in the courts, but I have seen too many darn illustrations where they have really done a very bad job in resolving some of these business issues, and it might be better for us to get together and resolve them in an effective way together and get a bill here that would really do the job.

Mr. MOSSINGHOFF. I would accept that offer to reflect on and talk to our experts in the industry and see what we might come up with and discuss with you and the chairman.

Senator HATCH. All right.

Now, why would compliance with the disclosure section of S. 568, which requires disclosure of all process patents owned or licensed by the patentee with respect to a particular product be unduly burdensome to you, or to the patentee in this case?

Mr. MOSSINGHOFF. It is a totally unusual provision. The patent system itself is an objective system.

Senator HATCH. Yes, but I would think such information would be readily available to the patentee.

Mr. MOSSINGHOFF. Well, the number of process patents owned by any one of our member companies is readily available through the Lexus service system.

Senator HATCH. That is why it should not be too difficult a thing to give notice.

Mr. MOSSINGHOFF. I just think that naming the patents before you even have—you are wandering into litigation, obviously. It is before discovery applies. It is before you have the information. I think the industry experts are unanimous that there are just a series of bombshells or land mines waiting to go off in that totally unique and, in our opinion, totally unnecessary provision.

Senator HATCH. What we are trying to do is prevent infringement by having a mechanism in the bill to give effective notice. It seems to me that those materials and those disclosures are readily available to the patentee. I don't see any reason why responding to a request for disclosure would be such a burdensome thing.

I understand that you don't like it, but I don't see any reason for that. I don't think it is a burdensome, overregulatory, or bureaucratic approach. It certainly would give more notice and it certainly would, it seems to me, make the system work a little bit better. Just give some thought to that.

Mr. MOSSINGHOFF. It is viewed, Mr. Chairman, by the experts in our industry as having great potential for harassment of the companies and, as I say, it lays out a series of traps that——

Senator HATCH. Let's see if we can come up with some way to prevent harassment under that provision. But it seems to me you have got to give notice, and it should be in an effective way.

You also state that you oppose the use of the "substantial likelihood" standard in the notice section of S. 568. Do you believe, and do your people believe at PMA, that there is no potential for market intimidation of importers prior to the filing of a lawsuit?

Mr. MOSSINGHOFF. We believe that the patentee surely should be able to submit his reasons for belief or, in the other bill, the administration's bill, proof of notification is required. But substantial likelihood is a rather well-defined term of art, as I understand it, and we in effect have to include in our notification about what you would need to get a temporary restraining order or preliminary injunction.

That is a very high standard that you would have to do before you have discovery. In other words, the notice is given. At least in our industry, when new recombinant DNA processes are invented or discussed, this is known worldwide. It is a wide open industry.

We just think having to satisfy the substantial likelihood, which is a word of art in the judicial system, which you understand far better than I, that is too high a burden for someone who is merely going to tell somebody, we have a belief that you are infringing our process patent number 400,500,000. We think that is quite inadequate, rather than a substantial likelihood, which is virtually proving your case before you have discovery or any of the other opportunities.

Senator HATCH. Do you have a better way?

Mr. MOSSINGHOFF. Pardon?

Senator HATCH. Do you have a better way of preventing intimidation?

Mr. MOSSINGHOFF. I think the standard in Senator Lautenberg's bill that the patentee believes—he has to set forth in the notice his reasons why he believes the process was used in the manufacture; that is perfectly adequate for the U.S. concern to send that to his supplier, who presumably has indemnified him, hopefully, to say that I have this notice from company X; here is that patent that they have indicated; do you infringe it? And if you do, I would like to buy from a noninfringing source.

Senator HATCH. All right.

Thank you, Mr. Chairman.

Senator DECONCINI. The Senator from Iowa?

Senator GRASSLEY. Yes. I have a question for Mr. Mossinghoff.

I would like to have you tell me—does your company, or do your companies, currently disclose your product patents to companies upon request?

Mr. MOSSINGHOFF. They do not. In the almost 200 years of the U.S. patent law, that has not been a requirement for patent owners. The patent system is an objective system.

Senator GRASSLEY. I am saying, upon request.

Mr. MOSSINGHOFF. I think the answer is no.

Senator GRASSLEY. All right.

Mr. MOSSINGHOFF. The answer is no.

Senator GRASSLEY. Now, I would like to have Mr. Massengill comment on a question that was asked of you, Mr. Mossinghoff, and that is in regard to the process patent bill that the House Judiciary Committee ordered reported last week, your comments on that.

Mr. MASSENGILL. I think we would be prepared to support that bill. I would suggest, though, that the provision regarding the court's ability to establish what is a reasonable time could invite abuse, and there should be, at least in the legislative history, a

finite time established that would be considered reasonable rather than leave it open ended for the courts.

Senator GRASSLEY. And then I would like to have both of your comments on what you would consider the most important aspect of the Hatch-DeConcini bill, that, if you could change it, what would that be?

Mr. MOSSINGHOFF. Senator, it would be, from our point of view, the provisions having to do with this mischievous request for disclosure that we have already discussed, and that is intricately tied into the 6-month, 18-month periods, and I think that, whatever the Congress decides to do, it should not give comfort to those who would use this to say that now Congress has endorsed compulsory licensing as a general principle.

Mr. MASSENGILL. I think the first provision that I would try to improve would be the requirement for notice. I believe that the rights and the legitimate interests of the parties affected by this legislation could be served by a less stringent notice requirement.

Senator GRASSLEY. I have no further questions, Mr. Chairman.

Senator DECONCINI. Thank you, Senator Grassley.

Thank you, gentlemen. I have some questions that I will submit to you—Mr. Mossinghoff, particularly—as to the notice provision which time does not permit me to go into here. If you could respond to them from your own experience but also your association's position, mainly on the notice area, I would appreciate it.

Mr. MOSSINGHOFF. Fine.

Senator DECONCINI. Thank you.

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

Senator DECONCINI. Our next panel will be David Haarz, National Retail Merchants Association, and Alfred Engelberg, Generic Pharmaceutical Industry Association.

Mr. Haarz, we will start with you. If both of you could summarize your statements, due to time restraints, we have some questions, and your full statements will appear in the record, without objection.

## STATEMENT OF DAVID R. HAARZ, NATIONAL RETAIL MERCHANTS ASSOCIATION

Mr. HAARZ. Good morning.

I am an attorney in the legal department at K mart Corp. I am here today to testify in behalf of the National Retail Merchants Association.

NRMA members include 45,000 department, chain, independent, and specialty stores in all 50 States. NRMA members employ more than 3 million people and have sales in excess of $150 billion a year.

On behalf of NRMA and its members, I would like to thank Senator DeConcini and Senator Hatch and the subcommittee for the opportunity to file a written statement and to appear at this hearing today.

NRMA is supportive of efforts to make U.S. industries more competitive through innovation. Retailers are proud to be the vehicle through which new technology is often delivered to the general public.

We are optimistic that we will ultimately be able to support process patent legislation because of the recognition shown to retailer and consumer concerns during the informal discussions with the subcommittee staff.

There are three particularly troublesome areas for retailers with regard to process patent legislation. These are the threshold of liability, the notice provision, and the presumption of infringement. I would like to briefly address these concerns.

Current U.S. law does not impose liability for process patent infringement upon a retailer, even if the product is manufactured in the United States. This is a recognition that it is unreasonable to expect a retailer to know the processes by which the thousands of products it sells are manufactured.

H.R. 1931, the Moorhead bill, which was recently approved by the House Judiciary Committee, recognizes the retailer's position. Unfortunately, it does not go far enough, in our opinion, and we would urge that the Senate eliminate any retailer liability with regard to commercially reasonable quantities of product in possession, in transit, or on order at the time of the receipt of a notice of infringement.

Process patent legislation should continue the recognition of a retailer's position. Such a provision is not a compulsory license but a limitation of liability similar to limitation of liability currently in U.S. patent laws in the event a patent owner fails to provide notice by marking its patent number on its product.

We do not believe that the request-for-disclosure provision contained in Senate bill 568 is a workable mechanism for dealing with retailer concerns. The request for disclosure would require retailers to undertake an expensive and expansive search with regard to each and every component of each and every product the retailer is considering purchasing.

With regard to the notice necessary to establish liability, process patent legislation must require patent owners to provide written notice of infringement detailing facts and circumstances establishing that a given product was produced using a patented process. The Moorhead bill recognizes this, and the notice provision it contains is preferable to those contained in other bills. Any lesser standard of notice will provide patent owners with the power to drive competing products from retail shelves through vague or conclusory notices of infringement.

Our last concern is with the presumption of infringement. We believe that this presumption is unnecessary, particularly in light of the fact that a patent owner is already entitled to a strong presumption of validity.

We would strongly encourage the subcommittee to create as broad a jurisdictional base as possible for patent infringement of processes so that the U.S. patent owner will be able to go after in court the real party in interest, the product manufacturer.

The patent owner is in the best position to know the technology involved in a particular manufacturing process, and he is in the best position to prove that a product was manufactured in accordance with such process. The other side of the coin is that the manufacturer of our product would be in the best position to answer those charges.

If, in a particular case, a patent owner is unable to prove infringement because of the action of a foreign manufacturer, a court can deal with that problem on an ad hoc basis and, if necessary, presume that the product in question was manufactured in accordance with the patented process. However, a blanket presumption of infringement is not necessary and will encourage patent owners to seek overly broad discovery in the hope that the foreign manufacturer will refuse such discovery, thereby establishing the presumption.

Giving patent owners a presumption of infringement along with the current presumption of validity can only lead to coercive use of patents against retailers.

We are ready and willing to work with the subcommittee and its staff with regard to any working proposals which may be developed.

Thank you.

[Statement Mr. Haarz follows:]

# STATEMENT OF THE NATIONAL RETAIL MERCHANTS ASSOCIATION

## SUMMARY

1. The National Retail Merchants Association ("NRMA") opposes S. 568, S. 573 and S. 635 because each, as currently drafted, would impose unfair, unmanageable and inequitable burdens on retailers and consumers, which would lead to higher costs to retailers and higher prices to consumers.

2. NRMA believes, however, that process patent legislation can be adopted that would protect U.S. patent holders and encourage inventiveness, while at the same time protecting retailers from the inequities of the currently proposed bills.

3. Process patent liability should arise only if adequate notice is provided.

4. Process patent liability should be premised only on an opportunity to avoid such liability.

5. A presumption of infringement is unnecessary.

* * *

The National Retail Merchants Association ("NRMA") respectfully submits this statement in connection with the Subcommittee's consideration of S. 568, S. 573 and S. 635. NRMA is the nation's largest trade association for the general merchandise retail industry. Our members operate 45,000 leading department, chain, independent and specialty stores in all 50 states, employ more than 3 million people and have annual aggregate sales in excess of $150 billion.

The National Mass Retailing Institute ("NMRI") also endorses this statement on process patent legislation on behalf of its members. NMRI is a national trade association representing over 125 major discount retailing chains which operate over 20,000 stores in all 50 states.

Whereas the proposed legislation seeks to achieve laudable goals -- the strengthening of intellectual property rights and technological innovation in the United States, and in some respects addresses points raised by NRMA in opposition to similar legislation in the last Congress, these attributes are still far outweighed by the unfair, unmanageable and inequitable burdens and costs that such legislation, as currently drafted, would place upon innocent U.S. retail merchants, and ultimately upon consumers of every conceivable type of retail product.

NRMA, therefore, strongly urges that if the Subcommittee determines that process patent legislation is warranted to encourage and foster U.S. technological inventiveness, such legislation should be drafted so that it does not impose unnecessary and clearly unjustifiable costs on retailers and consumers. NRMA believes that such an accommodation is possible. However, S. 568, S. 573 and S. 635 fall short in doing so.

I. S. 568, S. 573 And S. 635 Would Impose Unfair, Unmanageable And Inequitable Burdens On Retailers And Consumers

As currently drafted, each of the proposed bills would lead to higher costs of doing business for retailers, which would be translated directly into higher consumer prices. This result is inevitable because the bills would permit the owner of a patented process to recover monetary damages from anyone who uses, sells, or imports into the United States a product made pursuant to the patented process.[1] Such damages would be recoverable, except in limited circumstances provided for in S. 568, from the time the alleged infringer is given notice of the purported infringe-

1. Under current law, a retailer does not infringe a patent owner's rights by importing or selling a product manufactured in accordance with a process patent. This is true even if the product was manufactured in the United States.

ment,[2] and a presumption of infringement would exist whereby the patent holder would only need to show that it is substantially likely[3] that the product was made by means of a patented process, and that he has made a reasonable effort, but was unable to ascertain, the process used. The user, seller or importer, each of which could be a retailer, would then have the almost impossible burden of proving a negative: that the product was not made by use of the patented process.

These provisions would place entirely innocent retailers in the impossible position of choosing between exposure to potentially ruinous monetary damage claims for patent infringement, or the equally costly and time consuming task of undertaking a fact finding mission to ensure themselves that goods purchased from every one of their suppliers, domestic as well as foreign, were not produced pursuant to a process protected by a U.S. patent. The inequities of imposing such a burdensome, unfair, and enormously costly legislatively created dilemma upon a retailer -- who has no part in, and ordinarily no knowledge of, the processes with which products on his shelves are made -- are manifold. Retailers buy and sell thousands of different products. For the most part, these are finished products, any one of which may have hundreds of components. Retailers have no way of knowing the source of these many components, particularly for complex products. Generally, the merchandise has passed through several steps in the chain of distribution; from the manufacturer, to a wholesaler, then possibly to a distributor, and only then to the retailer.

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2. S. 568 and S. 635 would also permit the recovery of damages even if no notice is given, if an alleged infringer had knowledge of the purported infringement.

3. Under S. 573, rather than a showing of substantial likelihood, a patent holder would be required to show a high degree of probability that the product in question was produced by the patented process.

Under these circumstances, to force a retailer to prove that a certain process was not used far up the distribution chain would entail monumental costs, and absolutely no guarantee that an investigation would provide the retailers with any greater insulation from potential liability. A presumption of infringement would merely add insult to injury. There is no way that a typical store owner could meet the burden contemplated by the proposed bills for the hundreds of different items on its shelves without spending a fortune in time and money, conducting investigations, paying lawyers, etc., both here and abroad.

The notice requirement that would trigger a retailer's liability for damages, specifically under S. 635, is also unreasonable. Under such a standard, a retailer would either have to pull allegedly infringing merchandise from its shelves during its efforts to determine whether there is an infringement, or face liability for those sales. The damages and presumption sections of the bill would also encourage patent-holding suppliers to engage in coercive, anticompetitive tactics by claiming that any colorably similar imported goods were produced in violation of their patent rights. Knowing that a retailer is likely to remove allegedly infringing products upon notice, and that most retailers cannot afford the time it takes to resolve a claim, some suppliers would simply give such notice and drive their competitors' products from retailers' shelves. Thus, in practice, the scope of the patent would be extended far beyond its legal bounds.

If retailers are faced with the costs of compliance and the risks of liability contemplated by these bills, the price of merchandise will rise. If retailers are forced to insure themselves against infringement liability (if insurance is available at all) the costs will be extreme. The

expenses of suit, of jettisoning inventory upon notification of infringement, and of damage awards, will take their toll. All these costs will be borne by consumers.

Of course, the burdens of this legislation will extend far beyond increased costs. Retailers will simply stop stocking whole classes of products whose methods of manufacture cannot easily be verified, and will make available to their customers fewer types of products.

If all of these undesirable results were inevitable for American innovation to be protected, the proposed bills might be worth the price. However, such is not the case. As discussed below, process patent legislation can be adopted which would protect U.S. patent holders and encourage inventiveness, while at the same time protecting retailers from the sharp effects that they would face if the currently proposed bills were enacted.

## II. Process Patent Liability Should Arise Only If Adequate Written Notice Is Provided

Retailers who do not make or use a patented process should have liability for process patent infringement only after adequate written notice is provided. To permit otherwise would be diametrically contrary to any sense of equity; innocent retailers who handle thousands of different products cannot be expected to determine whether a product -- or any component of that product -- was made pursuant to some patented process.

S. 568 goes far to establish an adequate, yet unburdensome, standard for notice. Under this bill a notice of infringement would have to "set forth facts which are sufficient to establish that there is a substantial likeli-

hood that the product was made by the infringing process."[4] This standard would be the minimum the Subcommittee should find acceptable, if it also included the requirement of setting forth facts sufficient to show that the patent in question is valid. To permit any less would be contrary to the policy and letter of Rule 11 of the Federal Rules of Civil Procedure which requires a "reasonable inquiry" to determine that allegations of unlawful conduct are "well grounded in fact." Moreover, a lesser standard would also expose a retailer to damages even before a lawsuit is filed, even though the retailer would have no way of knowing -- or necessarily finding out -- whether it is actually infringing.

Thus, there are many reasons to require a notice standard as discussed above, and absolutely no reason not to. If process patent holders want protection against infringers, they should at least be required to come forward with well grounded facts based on careful investigation, not idle speculation premised on assumptions.

## III. Process Patent Liability Should Be Premised Only On An Opportunity To Avoid Such Liability

A retailer who does not make or use a patented process also should be allowed a commercially reasonable period of time after receipt of a notice of infringement to dispose of allegedly infringing products which were purchased or ordered prior to notice. The equity of providing for such a grace period is again recognized by S. 568.

S. 568, however, does not go far enough. It would provide a grace period for products in a retailer's inventory

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4. S. 573 would only require that the notice specify the patented process claimed to have been used, and the reasons for the belief that such process was used in the production of the product. S. 635 contains no substantiation requirement at all.

or on order at the time of notice, but only if such products were obtained from a party in the United States who did not use the patented process. If the allegedly infringing products are purchased overseas, or from a U.S. manufacturer who allegedly used an infringing process, a retailer could, for six months after notice, limit its liability to a reasonable royalty, but only if it followed a totally unworkable "request for disclosure" procedure.

There is no basis to limit a retailer's grace period in this manner. Regardless of where a product is purchased -- whether in the U.S. or overseas -- a retailer will face the same burdens under the proposed legislation. There is simply nothing that can support the assertion that retailer/importers are better equipped to act more vigilantly as compared to domestic purchasing retailers. In fact, many retailers who import products for resale in the U.S. do so because of the lower cost of foreign goods, which in turn permit cost savings to be passed on to consumers. If retailer/importers are subjected to a more stringent standard in investigating their sources of supply than their domestic buying counterparts, such cost savings will disappear, and consumers again will be the ones who take it on the chin in the form of higher prices.

Similarly, a lesser grace period for retailer/importers cannot be justified on the ground that such retailers would have greater access to information from a foreign supplier than would a process patent holder. First, all that would be needed for a process patent holder to obtain jurisdiction over a purportedly infringing foreign manufacturer would be for the manufacturer to have "minimum contacts" with the United States.[5] To satisfy this standard it

5. See World-Wide Volkswagen Corporation v. Woodson, 444 U.S. 286 (1980).

would only be necessary for the patent owner to show that the foreign manufacturer introduced products into the stream of commerce of the forum state.[6] Second, the patent holder has a decided advantage over a retailer in obtaining proof on the question of infringement. The patent holder starts out with the necessary technical expertise, which a retailer, especially a small one, is unlikely to have. The patent owner also could, in a suit against a purportedly infringing foreign manufacturer, avail itself of the time-tested and already existing rights to discovery provided by the Federal Rules of Civil Procedure.[7] Discovery from foreign manufacturers may also be available under the Hague Convention.[8]

Nor would the request for disclosure procedure contemplated by S. 568 be workable or effective. A typical retailer stocks thousands of items, which in turn might include thousands more components. It cannot be expected that such a retailer would be able to identify each likely holder of a relevant process patent, many of whom might be independent inventors or small business owners. However, under a request for disclosure procedure, if the retailer is to have any comfort in purchasing and reselling a particular product, that is precisely what it must do. Thus, here too,

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6. Id.; Hedrick v. Daiko Shoji Co., Ltd., 715 F.2d 1355, 1358 (9th Cir. 1983). But see Asahi Metal Industry Co., Ltd. v. Superior Court of California, 55 U.S.L.W. 4197 (Feb. 24, 1987) (4 to 4 vote on question of whether mere foreseeability that products would be used or sold in forum state was sufficient to warrant exercise of personal jurisdiction over foreign defendant).

7. See, e.g., In re Anscheutz & Co., GmbH, 754 F.2d 602 (5th Cir. 1985); Beckman Instruments, Inc. v. LKB Products AB, 229 U.S.P.Q. 78 (D.Md. 1978).

8. Multilateral Convention on Taking of Evidence Abroad in Civil and Commercial Matters, done 18 March 1970 [1972], 23 U.S.T. 2555, T.I.A.S. No. 7444.

technical experts, lawyers and others would have to be retained to make sure a search is conducted properly and responses from potential claimants are complete and satisfactory. Needless to say, such efforts would involve costs, which would no doubt be passed on to consumers who will face yet higher prices.

A request for disclosure procedure would also improperly encourage process patent owners not to disclose complete information. By not identifying its patent rights, a patent owner could induce an unknowing infringement and exact, under S. 568 as presently drafted, a royalty from the duped retailer. For this reason alone, therefore, the request for disclosure procedure should be rejected.

Finally, the argument that a grace period should not be permitted because it would be equivalent to the granting of a compulsory license, is misplaced. Compulsory licenses traditionally have been viewed as contrary to the essential principle of the patent laws which is to encourage inventiveness. If compulsory licenses were permitted, this principle states, inventors would not be able to recoup their investment in developing a patented item because the product would be available from a number of other sources, and, therefore, inventors would be less inclined to engage in research and development efforts. This policy rationale, however, loses its appeal and weight when applied to the type of grace period as is proposed here. Such a provision would only permit an unknowing retailer the limited ability to dispose of merchandise ordered or received <u>before</u> receiving a notice of infringement. Any sales of infringing goods purchased after notice would give rise to liability, and, since the patent holder would be advised of the retailer's source of supply, the availability of additional infringing

goods could be shut off promptly.[9] Hence, the disincentives that might result from a compulsory license, simply, are unlikely to exist if a limited grace period for innocent, unknowing retailers is allowed.

For these reasons, NRMA submits that retailers should be permitted a commercially reasonable period after notice of infringement is received in which to sell their inventory of products that were purchased or ordered prior to such notice. The basic concept for such a grace period is contemplated in S. 568; however, the terms of that bill as currently drafted need to be expanded so that all retailers will be adequately protected.

IV. Presumption of Infringement Is Unnecessary

While the use of a presumption may appear to be an appealing solution to the perceived problem of patent owners being unable to determine whether a particular product was produced by a patented process, such a presumption has no place, or any justification, in process patent legislation of the type contemplated here.

As discussed earlier, a patent holder has a greater chance, as compared to a retailer, of obtaining information and proceeding against an infringing manufacturer, wherever located. Requiring a patent holder to go against the real infringing party is also warranted, because if it were the retailer's obligation, the extra cost that would be passed on to consumers would be enormous.

Furthermore, the easy target of a suit under the proposed process patent legislation will often be a retailer

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9. S. 568 only provides a grace period if the retailer discloses the identity and location of the party from whom the products were purchased. If the source of the goods is an overseas entity, the patent holder could block further entry of infringing goods into the U.S. pursuant to 19 U.S.C. § 1337 and 1337(a).

well down in the chain of distribution. With little incentive to fend off a patent infringement suit, the likely response of such a merchant to even the threat of litigation would be to settle the dispute by discontinuing the allegedly infringing product line. Hence a statutory presumption making the retailers' defense legally more difficult (and less likely) makes little sense.

V. Conclusion

For all the reasons discussed, NRMA and NMRI strongly urge that if the Subcommittee believes process patent legislation should be adopted, such legislation should be drafted in a manner which will not impose significant, unnecessary and inequitable costs and burdens on retailers and consumers. NRMA and NMRI believe that effective legislation can be adopted without such negative effects, and the proposals set forth above would serve as a reasonable means to ensure such a result.

Senator DECONCINI. Thank you, Mr. Haarz.
Mr. Engelberg?

## STATEMENT OF ALFRED B. ENGELBERG, PATENT COUNSEL, GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

Mr. ENGELBERG. Thank you, Senator.

My name is Alfred Engelberg, and I am here as counsel to the Generic Pharmaceutical Industry Association.

I would like, if I can, to get directly to what I think are the definitions of the problem and the solution that appear in S. 568.

Let me say at the outset, and I think it is fairly well known, that we, the Generic Pharmaceutical Industry Association, started out dead against any process patent legislation because it followed directly on the heels of a very delicate negotiation involving patent rights in the pharmaceutical industry from which process patents were excluded by virtue of a uniform recognition that the generic manufacturers were not involved in the manufacture of bulk chemicals and were not in a position to verify what their suppliers were or were not doing abroad.

We, nevertheless, in an effort to find a good-faith solution to the needs of a more broadly based class of process patent owners, participated in the negotiations which led to S. 568.

The problem is a very simple one. This legislation does not just address high-tech products, the amorphous metals of Allied or the biotech products that some have referred to here. It affects every

commodity, every piece of fabric, every ballpoint pen that moves in commerce, and it says that we are now going to have these transactions dominated by inquiries between buyers and sellers as to how these products were made, and that we are going to have these inquiries take place and have this liability fall on the buyer no matter how big or small a transaction and no matter how many processes might be involved and no matter how many alternate processes might be involved, or whether we are talking about old or new products.

This is an incredible new burden on commerce, and I think we need to be careful here that we do not make patents dominate commerce rather than have patents work for commerce, which is the intention of all these bills.

Looked at from the perspective of patent law, however, we have a new wrinkle here, and that is that the purchaser of the product does not have any of the facts to defend himself. He did not make the product. He does not know how it was made. And, in the ordinary course of business events, those kinds of disclosures simply are not made between buyers and sellers. They are made if and when a problem arises.

So we approach this problem from the point of view of saying, how can we deal with this and not have the potential for harassment that is here when you consider the broad range of products?

I might say as an aside here, Senator, that there has been only one process patent case involving pharmaceuticals in the last few years. That case is pending before the ITC, and the ITC has a lot of safeguards for process patent owners.

In that case, it turns out that the process patent was purchased by the patent owner from a Japanese company. There were multiple processes for making the same product. There was no economic value to the process to any competition, and in fact there was a noninfringing as well as an infringing process available, the bottom line of which is that there is a proceeding going on in the ITC right now in which a harassment charge has been leveled by the alleged infringer against the patent owner, and precisely the kinds of shenanigans and arguments are going on in a courtroom that we are trying to avoid with this legislation.

Now, what are the solutions? The first solution that everybody agrees to, or seems to agree to, is that there is no liability without notice. From what we heard this morning, there seems to be more agreement than there was before that that has to include some disposal of inventory.

The purpose of the numbers, the 6 to 18 months, did not come from GPIA, and in fact did not come from the retailers. The purpose of the numbers came from the patent owners.

There is a misperception afloat about the numbers. The numbers are not open-ended, 6- or 18-month periods in which you can acquire new goods and dispose of them. The numbers define a cutoff, and the purpose of a cutoff is to enable parties who might otherwise litigate to have a day certain on which they can look at the marketplace and say, if there are any goods out there after this date, no matter how much inventory you had to start with, those goods can no longer be out there or those goods are subject to the full penalties of the patent laws.

So the only thing the numbers accomplish is to keep people out of court. They define cutoff dates that everyone can understand in a very simple fashion.

Now, we offered, as is clear in S. 568, to pay for the privilege—we as the generic industry. The retailers did not, I believe, and they have good reasons why they do not want to. We offered to pay for the privilege of disposing of that inventory, and it was rejected as being a compulsory license. We will be happy to dispose of the inventory without paying if that is the compromise.

The second point deals with the substantial likelihood, the notice test. There, you have to start with the notion that the party being accused of the infringement is a stand-in surrogate defendant. He is not the person that is really charged with the act of infringement—it is his supplier—and he does not have the facts readily in his hands to defend himself.

As the bill admits as its ultimate premise, those facts may never become available. If the patent owners thought that those facts would always become available, they would not insist on a shifting of the burden-of-proof provision as a keystone of this bill.

So we are dealing with a situation where the facts may never hit the table, and we are dealing with a situation where the processes for making every product in commerce are involved.

The purpose of the notice is to say that if there are multiple processes, if the patent infringement claim relates to a product which can be made by a multitude of ways, there have to be reasons, rather than wishful thinking, for an assertion of infringement.

If we are talking about a new DNA molecule which cannot be patented because it duplicates a naturally occurring material and was not commercially available until the process was discovered, the notice is going to be very simple. The patent owners are going to come in and say, "Until yesterday, there wasn't any way to do this, and if you copied it the day after, there is a high likelihood that it was an infringing process."

If the process relates to refining salt or producing salt, there may be 10 processes. It is not enough to come in and say, as Mr. Mossinghoff would suggest, "I own this patent; I believe I might get lucky and catch you in infringement."

Now, there is another misconception afloat about the substantial likelihood provision, and that is that it does not cut off the right of the patent owner to bring a lawsuit, and it does not cut off his right to take discovery. All the notice provision does is cut off the right to have a threat of damages against the person charged with infringement while the facts are being developed to determine whether or not there is a substantial likelihood of infringement.

So, in effect, the only deprivation that the notice requirement would cause is a deprivation of leverage. It would set up a circumstance that, while the case is in a posture where neither the innocent purchaser nor the patent owner knows whether or not there is infringement, there would not be any financial liability. When the facts filled up to the point where the alleged infringer could no longer bury his head in the sand, he would begin to be liable. And it is a fair balance, recognizing that you are putting a burden on an innocent purchaser.

The last issue is the request-for-disclosure issue. Here, I think, we have a very interesting question of good faith because the patent owners say, what we really want is for people not to trespass on our rights. We say, "We don't want to trespass on your rights, but how do we determine that we are not trespassing on your rights?"

The response comes back, "Well, do a patent search. That's what everyone else does." There is a flaw in that argument. If the patent covers a product, then anyone can do a patent search. You have the product in one hand. You do a search and you get the relevant patents, and you make a comparison. Any kind of infringement study of any patent involves a comparison between the thing accused and the patents.

The problem with process patents is, the party charged with infringement does not have the patents, on the one hand, and does not have the process, on the other hand. All he has is an accusation.

So if I wanted to go into business tomorrow and buy a chemical, and I wanted to avoid infringement of Lilly's patents—and I had this experience within the last 3 months—I have to know what I am looking for. And I did not have any description of the process I was looking for because the foreign manufacturer would not give it to us. He said there was no problem and we should trust him. We said, "We would like to make sure." So we went and did a search, and we came up with about 300 Lilly process patents in the general area. We had no way to determine which ones might or might not be applicable, if any.

Our suggestion in this area was that if we could get that information up front, we would then have something we could go to the foreign suppliers with and say, "Look, this is what you have to indemnify us against; this is what you have to assure us against. And why should we all waste your time? If you are doing this, we are going to be out of business the day after we start."

The patent owners do not want to comply, and they do not have to do any studies. It is foolish for them to come in here and say that they do not know which of their own patents cover their own products, which is all we are asking them to disclose.

It seems to me that, if we are going to take this out of the area of gamesmanship, and we are going to put purchasers in the middle of a fight between competing manufacturers, we have to give them the tools to defend themselves, and that is all the request-for-disclosure provision does.

One last comment, and that is, Mr. Mossinghoff mentioned indemnification. The premise of this bill is that you cannot get at the foreign suppliers. You cannot get discovery from them. You cannot get them into a U.S. court. You cannot get jurisdiction over them to make them behave as you would like them to behave.

If that is true, what is the indemnification worth? The indemnification is worthless. What the patent owners want to do is shift the burden of their inability to get at these foreign manufacturers to the people who deal with them. We are willing to accept that burden, with fair limits. They are not willing to give us the fair limits.

[Statement of Mr. Engelberg follows:]

STATEMENT OF

ALFRED B. ENGELBERG

PATENT COUNSEL

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

SUMMARY

. S.568 is identical to S. 1543 which was unanimously passed by this committee, the Senate Judiciary Committee and the full Senate in the 99th Congress.

. S. 1543 resulted from intense negotiations led by Senator Mathias and ultimately agreed to by PMA, GPIA, NARDS, NRMA, Allied-Signal, Standard Oil, Merck, Lilly, Cyanamid, International Biotechnology Association and many others.

. The diverse group of supporters accepted S.1543 because it gave important additional protection to process patent owners while insuring that non-manufacturers would not be subject to undue harassment based on claims relating to the manner in which the products which they purchase are produced. Everyone involved in these negotiations ultimately recognized that there are substantial practical and commercial problems which make it impossible for purchasers to monitor the manufacturing activities of their suppliers.

. S.568 fully protects the legitimate interests of patent owners while insuring that innocent, non-manufacturing purchasers receive adequate patent information and infringement notice to prevent or avoid unneccesary litigation or draconian damage awards with respect to inventory acquired prior to a claim of infringement.

. S.568 is primarily opposed by patent lawyer groups who fail to recognize that the primary purpose of the patent laws are to foster productive economic activity and not merely to foster full employment for patent lawyers or to satisfy an intellectual desire for simple legislation even though such simplicity produces inequity.

. Groups like PMA, which supported S.568 last year but oppose it this year, view each session of Congress as a new opportunity to press for a "wish list" of unfair legislation designed to further increase the already bloated profits of member companies. These groups should carry a heavy burden in attempting tc pursuade Congress as to the bona fides of their current position in view of their support for S. 1543 last year.

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## The Case For S.568-The Hatch-DeConcini Process Patent Bill

In the 99th Congress, the Senate Judiciary Committee and the Senate unanimously passed S.1543. That bill was sponsored by Senator Mathias and was a compromise supported by a broad coalition of corporations and trade associations including Allied Chemical, Corning Glass, Standard Oil, Merck, Lilly, Cyanamid, International Biotechnology Association (IBA), Pharmaceutical Manufacturers

Association (PMA), Generic Pharmaceutical Industry Association (GPIA), National Association of Chain Drug Stores, National Association of Retail Merchants and other consumer and retail groups. S.568 is identical to S.1543.

This paper has been prepared by GPIA to explain why and how the compromise embodied in S.1543 was achieved and why it should be enacted in this session of Congress.

I. Background

Under current U.S. patent law, a patent is infringed only if the claimed invention is "made","used" or "sold", within the United States, without the consent of the patent owner. If the claimed invention is a product, such as a chemical compound, the manufacturer of the compound "makes" the product; distributors, wholesalers and retailers "sell" the product; and the ultimate consumer "uses" the product. Thus, they are all separately and equally liable for patent infringement. If, however, the patented invention is a process of manufacturing that same chemical compound, only the manufacturer "uses" the claimed process invention and is liable for infringement. No one else in the chain of distribution of the unpatented product produced by the patented process "makes", "uses" or "sells" the process.

These differences in who is liable for infringement are not "loopholes" in the patent law but rather arise from the nature of the patent grant and the fundamental differences between process and product inventions. The wholesalers, retailers and consumers of unpatented salt or sugar neither know nor care whether those unpatented commodities were produced by patented or unpatented refining processes and can not logically be charged with having made, used or sold the particular (and unknown) process actually used to produce the particular product which they purchased. The typical purchaser of a product does not know how that product was produced, has no responsibility or input into how it is produced, and has no means for finding out. Moreover, the vast majority of products are capable of being produced by many different processes and the actual process used usually can not be determined by inspecting the product and is a closely guarded trade secret of the manufacturer. Thus, to hold innocent purchasers liable for the unknown and undisclosed processes used to produce a product would merely serve to make them pawns in a dispute which ought to be resolved between the competing manufacturers of the product who have direct knowledge of the relevant facts.

One effect of the differences between product and process inventions is that a product manufactured outside the United States infringes a U.S. patent when the patented product is "used" or "sold" in this country even though the "making" of the product occurred outside the territory covered by the patent. Since processes are "used" only by the foreign manufacturer, and are not thereafter made

or sold, there is no act of infringement (making, use or sale of the patented process) in the United States. However, many years ago Congress recognized that a domestic manufacturer operating under a valid process patent could be unfairly injured by competition from products which were manufactured abroad without regard to the existence of a U.S. process patent. This potential problem was solved by Section 337 of the Tariff Act, which makes the importation into the United States of a product produced abroad by a process claimed in a U.S. patent an act of unfair competition and empowers the ITC to issue Exclusion Orders prohibiting further importation of such products.

In an ITC proceeding, the U.S. patent owner must file a sworn Complaint containing sufficient details to establish that process patent infringement has occurred. If, after an independent investigation by the ITC (which by law must be completed within 1 year) the requirements of Section 337 are satisfied, the Exclusion Order is entered. During the investigation, the foreign producer is normally required to disclose its process in order to resolve the issue of infringement and a failure to make a disclosure usually results in a presumption of infringement. Until an Exclusion Order is entered, the domestic purchasers of the imported products under investigation are free to continue with normal business activity, including continued importation and sale of the products. Thus, current law provides a remedy which rapidly restores exclusivity to the process patent owner in proven cases of process infringement without making U.S. purchasers liable for the infringing acts of foreign producers over which they have no control.

The proponents of additional process patent legislation claim that the ITC remedy is insufficient and that a direct remedy for process patent infringement under the patent law is needed. They claim that it should not be necessary for a party seeking relief under Section 337 to prove that (1) it has been injured or (2) that the patent owner is engaged in an efficiently operated domestic industry. Opponents of these changes point out that almost 50% of all U. S. patents are granted to foreign citizens and that many domestic companies practice their patented processes abroad to take advantage of lower labor costs. The ITC was created to protect domestic manufacturers from unfair competition due to imported products. It is not a patent court. By maintaining a "domestic industry " requirement as a prerequisite to process patent enforcement, patent owners will be encouraged to exploit their process patents here thereby fostering the growth of domestic manufacturing jobs.

The merits of the foregoing positions are being considered in pending legislation to amend Section 337 and therefore do not provide a legitimate basis for new and separate process patent legislation. The main argument being made in support of process patent legislation which is not being addressed in the effort to amend Section 337 is that the ITC does not provide any recovery of monetary damages for past infringement.

II. The Initial Process Legislation Proposals

The concept of a damage award for extraterritorial process patent infringement does not, at first blush, appear to be an unreasonable concept. It is not until one takes a closer look at who would pay and the amount and circumstances of the payment that the blatant unfairness and imbalance of the original legislative proposals becomes apparent. For the first time in the history of U.S. patent law, the purchaser of an unpatented product, who did not make, use or sell the patented process invention, would bear the liability for the alleged use of the patented process by a third party in a foreign land. The fact that the purchaser of the product had no knowledge of the patent, no knowledge or expertise as to the process, was not involved in the selection or "use" of the process and was utterly unable to defend against the claim would all be irrelevant. Moreover, this liability for damages, including the patent owner's lost profits, costs and attorney's fees, would arise immediately upon receipt of a notice from the patent owner which contained a bare allegation that there "may be" process patent infringement without any supporting facts to establish that the patented process rather than some other process was used to produce the unpatented product. Indeed, the full potential liability would even have attached to unpatented products which the innocent purchaser had ordered or had in inventory before any self-serving notice of infringement was sent by the patent owner. Thus, a retail chain which purchased a conventional unpatented item, such as sugar, and placed that product on the shelves of its stores, could not sell that product without incurring liability, based on a claim that it "may have" been refined by a patented process.

The original bill did not merely propose to shift the monetary liability, it also shifted the burden of proving non-infringement to the innocent purchaser of the unpatented product. A provision in the proposed law would have shifted that burden to the purchaser if the foreign manufacturer failed to provide sufficient information about the process to permit adjudication on the merits. Obviously, if the courts are unable to pry this information loose from an unwilling supplier there is no real chance that an innocent purchaser would be any more successful. It is, of course, unfair to assume that a supplier's refusal to make disclosure of its manufacturing process is tantamount to an admission of infringement. The foreign manufacturer may own important trade secrets which provide a competitive advantage as compared to the patented process. Thus, avoiding the risk of disclosure of those secrets to a competitor could be more important than the loss of a customer, particularly a small one.

Proponents of process patent legislation claim that these enormous changes in the scope of process patent protection are necessary because they can not get jurisdiction over a foreign manufacturer who has no place of business in the United States and would be unable to actually prove an allegation of infringement or collect a damage award without the cooperation of the accused

infringer. Obviously, the innocent purchasers of products are in no better position. It is clearly unfair to force them to absorb the entire impact of an unproven allegation of infringement. If they are compelled to do so, process patents could become a strong instrument of unfair economic coercion. An innocent purchaser saddled with a substantial inventory; having no immediate knowledge of the salient facts needed to determine the merits of an infringement claim and no assurance that the facts would be forthcoming from a foreign source; and facing an enormous potential damage liability, is an easy prey for a bad faith claim of infringement. A threat of infringement coupled with an offer by the patent owner to withdraw the claim if the innocent purchaser is willing to switch to the patent owner as a source of supply of the unpatented product would be hard to resist irrespective of the merits or good faith of the infringement claim. Worse yet, in those cases where there is no immediate alternative source of supply and the process patent owner is unwilling to sell the unpatented product of the process, the coercive effect of the unsubstantiated infringement claim may create an unjustified monopoly over the unpatented product.

III. The Compromise

During the last several months of the 99th Congress, the imbalance of the original legislative proposals was recognized and the industrial proponents and opponents of process patent legislation were brought together in the hope of producing a more balanced approach. A compromise was reached which was embodied in S.1543. It failed to become law only because of the indefensible objection by the Patent Office that the compromise included provisions amounting to compulsory licensing of process patents. Compulsory licensing of patents is clearly anathema to the large corporations who participated in the compromise and they would not have supported S.1543 if it truly provided for compulsory licensing.

The compromise embodied in S.1543 recognizes that the innocent non-manufacturing purchaser of unpatented imported products can not be unfairly burdened with the total responsibility for the manufacturing activities of a foreign supplier but also can not be permitted to rely on its own ignorance for an indefinite period of time once a claim of process patent infringement is fairly and properly asserted. The provisions of S.1543 are all consistent with the idea of promoting good faith on both sides and of avoiding unnecessary litigation in an environment where neither the party asserting process patent infringement nor the purchaser of the product who is accused of the infringement is likely to be in a position to actually know or prove what process was used abroad. Specifically, S.1543 contains the following safeguards:

(a) A provision requiring that a notice of process patent infringement given to a non-manufacturing purchaser of a product must include facts sufficient to support a substantial likelihood of

infringement before any liability for damages begins. This provision does not mean that a notice which does not meet the substantial likelihood test can not be sent or that infringement litigation can not be started. It simply means that no damages will be awarded for the use or sale of a product by an innocent purchaser, unless and until sufficient facts are put forth by the patent owner to establish a meaningful basis for the infringement claim.

Obviously, in cases involving new technologies where a commercial product exists only because of the existence of a patented process for producing it, it will be simple for the patent owner to recite facts sufficient to establish a substantial likelihood of infringement. However, in those cases where the product giving rise to the infringement claim could have been produced by any one of several processes, the patent owner will be properly charged with the duty of setting forth a meaningful basis for its claim before it can subject an innocent purchaser with no knowledge of the process to financial liability. This limitation on the starting point for damages is the best way to prevent the use of process patents as an instrument of harassment.

(b) A provision limiting the damage recovery to a reasonable royalty with respect to products which the innocent purchaser had on hand or on order at the time a proper notice of infringement is received. This provision also limits the period of time during which that inventory may be sold to 6 months except in the case of retailers where an 18 month inventory disposal period is permitted. Since there is general agreement that an innocent purchaser should not be liable for process patent infringement by its supplier which occurred prior to notice, this provision was necessary to deal with commitments made by the innocent purchaser prior to the time a notice was received. Limiting damages for inventory (provided that the inventory is not artificially bloated) to a reasonable royalty represents a reasonable compromise between full liability and no liability.

This mitigation of damage provision is not remotely similar to compulsory licensing because it does not grant a continuing right to remain in business. Indeed, it does not permit any additional products to be acquired after notice and also limits the quantity of inventory which may be sold and the time in which it can be sold.

(c) A provision designed to reduce the likelihood of process patent infringement by encouraging communication between patent owners and purchasers of imported products prior to any importation of products. A manufacturer of a product would be required to identify any process patents which it owns or controls that cover processes for the manufacture of its own product. That identification would be made in response to a request for such a patent disclosure made by a party planning to purchase a directly competing product abroad. The purchaser would be expected to use that information to make a good faith effort to purchase products made by non-infringing processes.

While patents are public documents it is often difficult and expensive to cull the relevant process patents from the millions of

existing unexpired patents without the expenditure of large amounts of time and money and the high risk of incompleteness. To insure the cooperation of patent owners, the law would give an innocent purchaser of products produced by an infringing process additional time to discontinue an infringement if infringement occurs after a patent owner fails to disclose a patent and later asserts a claim that the undisclosed patent has been infringed. An 18 month period was estimated to be the reasonable time required to locate a new source of supply without disruption of the purchaser's business--a disruption which might have been avoided if the patent owner had disclosed the existence of the patent.

A requirement that patent owners cooperate in an effort to avoid trespass on their property rights is clearly reasonable. Under current law, a patent owner who fails to mark a product with the relevant patent numbers loses all right to recover damages until actual notice of infringement is given. Greater protection is clearly justified in the case of a process patent which is being asserted against a mere purchaser of an unpatented product. Not surprisingly, this provision is strongly opposed by the American Intellectual Property Lawyers Association (AIPLA) whose members earn substantial fees for conducting patent searches.

IV. The Arguments Now Being Asserted Against The Compromise

There are no new meritorious arguments against the compromise embodied in S.1543 nor are there any real prospects for a better bill. This is evident from the positions taken by AIPLA, Intellectual Property Owners Association (IPO) and others in testimony before the Senate Sub-committee on Patents at a hearing on February 17, 1987. These organizations merely wish to return to the original legislative proposals which were overwhelmingly rejected in the last Congress because of their blatant unfairness. The most recent arguments against S.1543 put forth by IPO and the responses to those arguments which appear below demonstrate a continuing unwillingness by the opponents of S.1543 to make a fair assessment of that bill. The arguments and responses are as follows:

> IPO Argument: S.1543 guaranteed the infringers the right to stay in business and pay a reasonable royalty for 6 to 18 months after receiving a notice of infringement which can be viewed as a form of compulsory patent licensing.

This argument clearly distorts the limited relief provided in S.1543. The compromise only allows for the disposal of inventory which was on hand or for which a binding commitment had been made prior to the receipt of a notice of infringement. It does not permit additional orders to be placed (unless there has been bad faith by the patent owner in refusing to identify patents in response to a request for disclosure). It provides for a maximum inventory disposal period of 6 months, except in the case of retailers who get up to 18 months, and it denies the benefit of these provisions to persons who had actual knowledge of infringement or who bloated their inventory.

IPO Argument: S.1543 makes exceptions to the principle that sellers and users of patented inventions, as well as manufacturers, are liable for infringement.

Under current law, a purchaser of an unpatented product does not "make, use or sell" the process by which that product is produced and is not liable for infringement of a process patent. This is true even if the process is practiced in the United States. Process patent legislation seeks to expand liability for process patent infringement to the purchasers of unpatented products even though they do not make, use or sell the patented process invention. It also indirectly seeks to extend the reach of a patent to the "use" of a patented process by a foreign manufacturer who is beyond the jurisdiction of the U.S. courts. Given the foregoing, it is plainly ridiculous for IPO to argue that S.1543 creates any exception to traditional principles of patent infringement. The entire purpose of the new law is to expand the definition of infringement so as to cover acts which have never before been regarded as infringement, namely, the use or sale of an unpatented product made by an infringing process.

IPO Argument: S.1543 established a complex "request for disclosure" procedure forcing patent owners in advance of litigation to make an expensive and risky analysis of whether their patents "could reasonably be asserted" against infringers.

This argument is based on a deliberate misconstruction of the relevant provision of S.1543. A patent owner is only required to identify process patents which it owns or controls and which could be asserted against its own products if the patents were owned by someone else. There is no requirement to evaluate any product produced by a third party. Under current law a product patent owner is required to mark its products with the numbers of those patents which cover the product. The failure to do so results in a waiver of all damages for infringement until actual notice of infringement is given. The "request for disclosure" provision of S.1543 is analogous to this patent marking requirement.

IPO Argument: S. 1543 imposed on patent owners a burden of showing a substantial likelihood of infringement in order to start liability for damages.

The provision applies only if the assertion of infringement is being made against a non-manufacturing purchaser of an unpatented product who has no knowledge of the process by which the product was actually made. Most of the proponents of process patent legislation insist that patent owners are not in a position to prove process patent infringement and that the new law would be ineffective unless it contains a provision which shifts the burden of proving non-infringement to the purchaser of unpatented products. Such a shift is permitted only after the patent owner establishes a substantial likelihood of infringement. Thus, a patent owner can not prevail in litigation against an innocent purchaser in the absence of cooperation from the foreign supplier unless it independently produces facts sufficient to meet the substantial likelihood test. If it can not meet

this standard when it first asserts a claim, it is unlikely that it will ever meet it. Process patent owners should not be permitted to assert unsubstantiated infringement claims to terrorize innocent purchasers based on a mere hunch that there may be infringement. The limitation of damages to claims setting forth a meaningful case will merely expedite litigation and eliminate harassment.

IPO Argument: The enactment of S.1543 might open the way for the same provisions to be incorporated into Section 337 of the Tariff Act of 1930.

The safeguards built into S.1543 are already part of Section 337. Under Section 337, the ITC will not start an investigation unless a Complaint is filed under oath by a corporate officer and sets forth detailed facts to support the basis for a claim of infringement. The ITC Office of Investigations conducts an investigation to verify the content of the Complaint and the ITC actually votes on the question of whether there are sufficient grounds to institute a Section 337 proceeding. If a proceeding is instituted, it normally takes at least 6 months to obtain a Temporary Exclusion Order and 1 year before a permanent Exclusion Order is entered. Until a finding of infringement is made and an Exclusion Order is entered, the purchasers of the accused products are free not only to sell their inventory without any liability whatsoever but also may continue to order and import normal additional quantities of product without any financial liability irrespective of the ultimate outcome. Importers are usually free to dispose of previously imported product in inventory provided that they have not stockpiled inventory. Thus, the provisions of S.1543, which impose monetary liability on innocent purchasers immediately upon receipt of a proper notice of infringement, including a reasonable royalty liability for inventory on hand as of the initial notice date, are clearly more onerous than Section 337.

It is no surprise that a compromise reached after months of negotiations between parties with diverse views would contain provisions which would draw criticism from some group. That is the essence of compromise. The circumstances under which that compromise was wrought were admirably suited to forcing a separation between need and greed on the part of the opposed viewpoints. S.1543 and its successor S. 568, should not now be lightly disregarded simply because some vocal dissenters did not get everything they wanted.

Senator DECONCINI. Thank you, Mr. Engelberg.

I do want to thank you and your association for your willingness to sit down and work on this last year. I know from your previous testimony that you would just as soon leave it like it is, but you are willing to address this because you obviously have a very important interest, but you are prepared to work toward a solution.

Mr. Haarz, let me ask you a question. I am interested in knowing from what Mr. Mossinghoff indicated about indemnity, do you always have an indemnity from all of your suppliers?

Mr. HAARZ. Yes, we most certainly do. However, the indemnity is only against damages and can only be enforced against the supplier where the supplier is willing to honor that indemnification. But more important is the aspect that it does not indemnify us against litigation.

Senator DECONCINI. Well, why don't you get indemnities that would——

Mr. HAARZ. Well, it is impossible to indemnify someone against a lawsuit. I mean, anybody who has got 60 bucks can go into a U.S. district court and file suit against K mart. No one can indemnify us against that.

Senator DECONCINI. No, I know that.

Mr. HAARZ. But, just as an example——

Senator DECONCINI. But that is not what we are talking about. We are talking about a genuine disputed process patent allegation against you, and why can't you have an indemnity that would include that? Have you considered that?

Mr. HAARZ. We do have an indemnity in our contract. But, at the same time, it involves K mart. Perhaps the best way is, within the past 2 weeks, while we were preparing for this testimony, K mart was served with a lawsuit. Let me just read the defendants in this case: the Tandy Corp., K mart Corp., R.H. Macy, Sears, Consumers Distributing, Caldor, Federated Department Stores, Rayod House, Royal Plaza, Service Merchandise, Stop and Shop, Arthur's Jewelers, Susan L Jewelers, Custom Imports, Sound-Town Electronics, and the Bargain Man.

That is a pretty good list of small and large retailers. It was filed in New Jersey, and our supplier happens to be in New York. There is no excuse for not naming the manufacturer. But that is what attorneys do these days.

Senator DECONCINI. Let me just pursue that because you are not answering me. Maybe you don't want to or maybe you cannot.

If that lawsuit goes against you and there is a judgment against you, do you have an indemnification with the supplier even though it is not named?

Mr. HAARZ. Yes. Yes, we do.

Senator DECONCINI. So then you have to go and collect with that?

Mr. HAARZ. That is correct.

Senator DECONCINI. All right. That is what I wanted to know. Thank you.

Now, you mentioned the Moorhead bill, which precludes damages against the retailer unless there are no remedies available against an importer. Am I correct that you support that?

Mr. HAARZ. We support that basic principle. We would encourage that it be made clear in the legislation that we are attempting to give jurisdiction over the foreign manufacturers if that is at all possible.

Patent infringement is a tort. Long-arm statutes deal with torts. We would encourage the jurisdictional limits of the court to be ex-

tended as far as possible, including the introduction of a product into foreign commerce that would come into the United States.

Senator DECONCINI. If S. 568 were implemented with an 18-month period, why would retailers object to that? Once valid notice was given, why wouldn't you want to comply once it became clear that you were using somebody else's goods improperly?

Mr. HAARZ. I am sorry; I don't understand.

Senator DECONCINI. Well, if you have 18 months' notice, as in S. 568, what is the problem with that? It seems like that is ample time to get your house in order, to go for your indemnity, to make corrective measures.

Mr. HAARZ. We would support that.

Senator DECONCINI. That is a long period of time.

Mr. HAARZ. We would certainly agree that 18 months is a long period of time to sell off our merchandise. We are not objecting to that.

Senator DECONCINI. Now, what about paying the royalty during that period of time?

Mr. HAARZ. Well, the question is, then, that is perhaps a balancing of the situation, and it is perhaps a workable solution. However, we are buying the product; we are setting the——

Senator DECONCINI. Yes, and I think you have a good point there: it would depend on what the royalty is.

Mr. HAARZ. Right, and I would also point out that that is going to lead to the dispute as to what the royalty is. It is also going to encourage an unscrupulous patent owner to wait until the retailer has got his merchandise to hit him with a lawsuit, because if he gives the retailer notice before the retailer buys the product, the retailer can say, I am not buying that product; I don't want it. He can just sit there, wait for the retailer to have the product, jump on the retailer, and get his reasonable royalty. And, believe me, that happens, not from the companies you are seeing here today, but some patent owners and their attorneys love to jump retailers.

Senator DECONCINI. My last question is, we talk about innocent retailers. Is Kmart an innocent retailer?

Mr. HAARZ. We believe we are. We do not get involved in the manufacturing.

Senator DECONCINI. You do not have any indication that some of the material that you are buying is gray market or anything else?

Mr. HAARZ. Well, that gray market is a somewhat totally unrelated——

Senator DECONCINI. Yes, it is, but what about the gray market? Are you innocent?

Mr. HAARZ. Well, gray market—we like to refer to it as parallel importation, and as you know, those are genuine products, and they do not involve patent infringement. We believe that we are innocent.

Senator DECONCINI. So you know what you are doing there. What about in the area of process patents?

Mr. HAARZ. Without being given notice, we have no way of knowing how the product is being manufactured, or any reason to inquire.

Senator DECONCINI. Do you mean you do not know from commerce and other people exchanging information? Isn't there a grapevine of information within your industry?

Mr. HAARZ. Well, certainly, we have our ear to the ground. If there is a rumor in Taiwan or in America or anywhere that this is a problem, we do look into it.

Senator DECONCINI. And what do you do? Do you refuse to take it?

Mr. HAARZ. We do a patent search. However, with a process—for instance, if we are importing this pen, we have got to look at the spring; we have got to look at the ink; we have got to look at how the ink supply is put in there; how the mechanism works.

Senator DECONCINI. All right. Do you do that?

Mr. HAARZ. With processes? No.

Senator DECONCINI. You don't do any searches of patented processes?

Mr. HAARZ. Because, under current law, there is a recognition under current law that that is not reasonable to expect a retailer to know that. Under current law, we are not liable for process patent infringement.

Senator DECONCINI. What if you hear that that pen is a violation of the process? Do you look at it then?

Mr. HAARZ. No.

Senator DECONCINI. Or do you just say, "Well, we will just take it in; we don't worry about that"?

Mr. HAARZ. Well, we may look at it; we may talk to our supplier. I think, if it were proven to us that that is an infringement, we would probably never touch the item.

Senator DECONCINI. All right. So you would have to have some tangible proof before you would begin to look at it?

Mr. HAARZ. Sure. Well, otherwise, the pen manufacturer who has got the competitive product is going to just make a conclusory notice to us and say, "It infringes."

Senator DECONCINI. Well, what if he does do that and it turns out that it is infringement? Wouldn't you consider that he is unreliable and you don't want his pens, too? Wouldn't he be a source of trying to tell you the truth?

Mr. HAARZ. Well, usually, the people who do that usually do not sell to K mart in the first place, so they would have no incentive to keep us on their good side. All they are trying to do is keep competing products that are sold at a lower price off the market.

Senator DECONCINI. You only buy from reliable suppliers?

Mr. HAARZ. Yes.

Senator DECONCINI. Mr. Engelberg, let me ask you a question. You made a statement that patents should work for commerce rather than the other way. Do you think that is the case now as far as process patents are concerned?

Mr. ENGELBERG. Yes. I think the system we have right now works better than the one we are trying to impose——

Senator DECONCINI. You do?

Mr. ENGELBERG [continuing]. In two respects. We have process patent liability in the ITC today, and there are some amendments being made to that to facilitate——

Senator DECONCINI. Do you think we would be better off to adjust it in section 337?

Mr. ENGELBERG. I think so, because I think, when you really come down to it, the difference between section 337 and what we are talking about here in terms of a fair bill here would—the only difference would be an award of damages, and the damages would really only apply in cases of willful and deliberate infringement.

Senator DECONCINI. You heard Mr. Massengill give the other side of that argument that, notwithstanding some changes in section 337, that we still ought to move in this direction?

Mr. ENGELBERG. I heard him say it, but I think, when you compare the two statutes side by side, particularly section 337 in the direction it appears to be going, that you are down to a question of when and under what circumstances will damages be awarded, and you have an institution in the ITC that inherently filters harassment because it has its own independent investigative staff and it has a subpoena power that reaches across the ocean and draws adverse inferences from the failure of foreign suppliers to cooperate.

It has in place many of the things that are tearing us apart in trying to negotiate this bill—already in place—plus it has some requirement of the domestic industry, which is very important, because if patents are going to work for commerce and for U.S. commerce, then we have got to start taking into account the fact that, last year, 54 percent of all U.S. patents were issued to foreign residents.

The patent system is nationally neutral and is not the kind——

Senator DECONCINI. It is not working on behalf of U.S. citizens; that is for sure.

Mr. ENGELBERG. It is working to the extent that U.S. citizens are making meaningful inventions, but there is a little bit of myth being created in the arguments that are being made to suggest that, somehow or other, we own all the patents, that American citizens own all the patents. Not so.

Senator DECONCINI. Regarding the notice issue you raise and its importance to your industry in order to compare patents, what about the situation where a company does not have the patent but has purchased the right to that patent? They may not want to disclose that because of their image or their position.

How do you protect them from not having to make that disclosure?

Mr. ENGELBERG. Well, our proposal was that they did not have to make it, but if they were not going to make it, they would have to recognize that they were exacerbating the injury to the innocent purchaser who had made an attempt to get the information and avoid infringement. The proposal as it evolved in S. 568 was that, in that situation, the innocent purchaser would get a longer period of time to get out of business, a period of time that was negotiated around the concept of how long it would take to find an alternate, noninfringing source of supply.

Senator DECONCINI. Well, would you think that you could construct it in such a manner that the notice would be of such a nature that they either own the patent or own the right to supply or produce or promote the patent, not having to make the distinction when they give you notice?

Mr. ENGELBERG. I think all we care about are the patent numbers. It is very crucial to us to avoid infringement, and we are doing a heck of a good job. There has only been one process patent suit involving pharmaceuticals in the ITC.

What we are concerned about is that part of the move away from the ITC was a tearing away of the safeguards in the ITC system, and we would like to put them back in this bill. We think if the number of charges of infringement against generic drug companies goes up as a result of this bill, it is going to be because of gamesmanship, not because we have changed anything we are doing, and that is what we are trying to avoid.

Senator DECONCINI. Thank you.

I do have a couple of other questions for you, Mr. Engelberg, which I would like to submit to you, if you could answer them for us.

Thank you, Mr. Haarz.

Mr. HAARZ. Thank you.

Senator DECONCINI. Our last panel is Mr. Robert Kline, American Intellectual Property Law Association; Mr. Richard Witte, Intellectual Property Owners, Inc., and Mr. John Tramontine, New York Patent, Trademark and Copyright Law Association.

Gentlemen, your full statement we will put in the record, and due to time, we will ask that you please summarize them for us.

Mr. Kline, would you begin?

## STATEMENT OF ROBERT C. KLINE, PRESIDENT, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

Mr. KLINE. Mr. Chairman, as you indicated, I am here testifying on behalf of and representing the American Intellectual Property Law Association, which is a national society of more than 5,300 lawyers engaged in all aspects of the practice of law relating to intellectual property rights.

Since you have indicated that our written statement will become part of the record, I will make just a very few brief comments, since, indeed, I have very little to add to several of the statements that have already been made; in particular, those of Senator Lautenberg, Commissioner Quigg, and Mr. Mossinghoff.

AIPLA supports the enactment of S. 573, S. 635, and S. 539. Several of the previous speakers reviewed the history of process patent legislation in the 98th and 99th Congresses, and we all applaud your efforts, Mr. Chairman, in moving forward early in this 100th Congress on this most important issue.

There are several points I would like to mention briefly which AIPLA feels are undesirable provisions, which are included in some of the proposed bills.

The first of these is the request-for-disclosure provision. It requires disclosure of information to a competitor which we believe is not needed in order to accomplish the objectives here. It could be viewed as shifting the burden of evaluating the scope of patents in advance of litigation, and it would also place a burden on a process patent owner to advise competitors whether the process patent owner might file an infringement suit in a hypothetical situation which might occur later.

The second point is the notice provision. Commissioner Quigg has already commented on this. AIPLA favors the notice provision as set forth in S. 573 and S. 635. The provision as set forth in S. 568 requires a notice of infringement "sufficient to establish that there is a substantial likelihood that the product was made by the infringing process." We believe this is a standard which is unreasonable and unwarranted.

Mr. Chairman, I believe most all of the points, as I indicated earlier, have been covered by several of the previous witnesses. I would just like to say that AIPLA stands ready to work with your subcommittee and your staff to achieve the end result here we all know must be achieved in order to provide effective intellectual property protection to owners of U.S. process patents.

I will be happy to answer any of your questions.

[Statement of Mr. Kline follows:]

STATEMENT OF

ROBERT C. KLINE, PRESIDENT

AMERICAN
INTELLECTUAL PROPERTY LAW
ASSOCIATION

The American Intellectual Property Law Association (AIPLA), which was founded 90 years ago is a national society of more than 5,300 lawyers engaged in the practice of patent, trademark, copyright, licensing, and related fields of law affecting intellectual property rights. AIPLA membership includes lawyers in private, corporate, and government practice; lawyers associated with universities, small and large business, and lawyers active in both domestic and international transfer of technology.

I commend this Subcommittee for continuing efforts to enact effective legislation to correct a long standing and now significant defect in the legal rights of United States process patent owners.

AIPLA supports the enactment of S. 573 (Lautenberg) or S. 635 (Thurmond) Section 113. AIPLA opposes the enactment of S. 568 (Hatch).

* * *

U.S. companies are currently losing sales in our own country to foreign manufacturers which use American owned technological innovations without authorization. U.S. business competitiveness is increasingly dependent on the ability to reap the benefits of U.S. patented products and processes. Foreign piracy of that technology is a serious and growing problem.

The real value of new manufacturing techniques is reflected in the resulting products. A new process may enhance the quality of the product produced. A new process may allow the product to be made for less cost. In some cases, the new process may be the only method of producing a new product. In all of these cases, the advantage to the process patent owner is realized by using or selling the product or licensing others to do so.

The legal principle of protecting patented process technology by making the sale, use, or importation of the product of the process an infringement is not a new untried idea. That principle is embodied in the European Patent Convention, the Community Patent Convention, and the laws of most industrialized countries including Japan, the United Kingdom, the Federal Republic of Germany, France, and Switzerland. The World Intellectual Property Organization (WIPO) is currently developing a treaty to harmonize patent laws the working draft of which embodies this principle. WIPO is advocating that the patent law of all countries provide this protection.

* * *

Active congressional consideration of process patent reform began in the 98th Congress. On June 23, 1983, Senator Mathias introduced S. 1535, a section of which addressed process patents. That section was a four and one half line amendment to 35 USC 271 which established that the importation, sale or use of the product of U.S. patented process was an infringement of that patent. These few lines of the bill would have given a U.S. process patent owner the protection needed.

During the succeeding years the potential effect of this amendment on infringers became the primary focus of congressional attention and that continues today. Several commercial interests which will have to respect U.S. patents rights or become infringers if the law is amended have and continue to argue for fairness. In effect, their position is that the process patent laws which exist in Europe and Japan are unfair. We disagree. There is no reason to believe the laws of these countries are unfair. The truth is that these countries provide their business enterprises with the protection that American businesses which create and own technology need.

We urge the Subcommittee to carefully evaluate these claims of unfairness before responding to them by adopting amendments which deprive the patent owner of needed protection.

* * *

The most persistent requestors of fair treatment are the Generic Pharmaceutical Industry Association (GPIA). They concede that there are almost always several different methods of producing the chemical products they buy. They choose to purchase these chemicals from foreign suppliers. They do so because, after investigating the marketplace, conclude this is the least expensive source of supply. Effective process patent protection would not prevent GPIA member companies from buying from foreign suppliers. However, it would require them to take reasonable measures to be sure their foreign suppliers are not p ating U.S. technology.

The fundamental question is whether it is effective public policy to allow GPIA member companies, or any other potential infringer, to ignore the rights of U.S. patent owners because they save money by doing so. Unless one believes that patent laws do not promote public benefit or are inherently unfair, the answer must be no.

The GPIA explains how difficult it would be to continue in business if the U.S. had the process patent laws which exist in the other industrialized countries. They do not explain why it is that generic pharmaceutical companies in those countries are able to successfully do business. GPIA claims that foreign suppliers would refuse to disclose how products are made. They claim that standard supply contract indemnification clauses against patent infringement would not be acceptable to foreign suppliers. If the foreign supplier was using a non-infringing manufacturing process, we question whether these fears are real.

Several retail groups claim the enactment of an improved process patent law would result in unfairness to them. Like the GPIA, these groups offer no evidence or even argument that retailers in other industrialized countries suffer unfairly from process patent laws. However, the fact is that U.S. retailers have successfully bought and sold patented products for many

decades without undue patent law related problems. Retailers buy and sell hundreds or even thousands of products over time. Many may be imported. Many of these products, in whole or part, have the potential of infringing U.S. product patents. Certainly retailers do not do patent infringement searches on each product sold. Rather, they rely on the legitimacy and business reputation of their suppliers, both foreign and domestic. Also, retailers protect against patent infringement liability, and other forms of potential liability, with indemnification and warranty provisions in supply contracts. The ability of retailers to successfully protect themselves against purchasing a product which may infringe a U.S. product patent is in no way diminished because the product may infringe a U.S. process patent.

The fact is that the GPIA member companies and retail companies choose to do business with foreign operators for financial reasons. Dealing with foreign businesses may well involve more risk than dealing with U.S. businesses. However, they are voluntarily assuming the business risks involved and should be prepared to accept the financial consequences. We fully understand why these business interests want Congress to minimize their financial risks and costs. S. 573 and S. 635 go a long way to do just that. However, they do so in a manner which recognizes that the purpose of this legislation is to deter foreign pirates and protect U.S. owned technology.

All of the pending bills contain a significant concession to infringers which greatly reduces the possibility of litigation by severely limiting potential damage liability. Liability for damages does not attach to infringing conduct which occurs before notice is received from the patent owner. Infringement is forgiven for all past conduct, save willful infringement, until that point. This concession fully satisfies any reasonable criticism that the legislation is unfair to businesses which

choose to buy imported products. In our view, more concessions are not needed or justified.

* * *

The specific provisions of S. 568 which we believe are unwarranted and unwise are Section 2(c)(3) "retail compulsory license", Section 2(c)(4) "general compulsory license", and Section 2(c)(5) "request for disclosure".

The "request for disclosure" provision is not only unknown in patent law but as far as we can determine is an unknown concept in U.S. law. Generally stated the provision would require a business to disclose private and perhaps confidential commercial information to a competitor for the purpose of assisting that competitor. The penalty for failure to comply is the loss of a property right for one year. Failure to comply includes failure due to an unintentional error. The public interest can justify laws which require the disclosure of private business information to Executive Branch governmental agencies which need to have it to perform statutory responsibilities. However, we cannot identify a public interest to be served here. This provision affects only private interests. If enacted, it would take away property rights of one private party to assist the business endeavors of other private parties.

Patent and Trademark Office public records show the ownership of all patents when issued. Public records do not show whether patent rights have been sold or licensed to others. Conversely, public records do not normally reveal whether a given company has purchased or licensed the patent rights of others. This business related information is privately owned by the parties involved. The owner or owners may or may not choose to disclose this information either publicly or privately to others. A federal law abrogating these ownership rights and forcing disclosure to benefit private parties or suffer a financial punishment is unprecedented because it is fundamentally unfair. Regarding potential patent infringement, it is also unnecessary.

All U.S. patents are public records. Patents are regularly "searched" for a variety of reasons. One common reason is to avoid making, using, or selling an invention already patented. This is called an "infringement search". Patent attorneys make searches, as do professional patent searchers. Some companies in the business of searching own software and databases which make them capable of doing highly effective searches. Companies with computerized searching capabilities often specialize in specific areas of invention such as chemical arts. If the purpose of the request for disclosure section of S. 568 is only to unearth information on patented processes, that information is already both public and available. Of course, a person or company must pay to have an infringement search made. This has been considered a normal cost of doing business by many people for many years.

A "compulsory patent license" law is one which prevents a patent owner from enforcing patent rights in court. Such a law deprives the patentee of the only legal right a patent provides; the right to prevent unauthorized use of the invention. Section 2(c)(3) is a compulsory license which totally extinguishes the rights of a process patentee for 18 months without compensation as to an infringer which makes retail sales. Then for subsequent infringers the same punishment is applied to the patent owner until the succession of infringers ends or the term of the patent expires. Section 2(c)(4) is a general compulsory license of 6 month or 18 month duration depending on the compliance of the patentee with the request for disclosure requirement. Remedies are limited to a reasonable royalty, only collectible by the patentee in the highly unlikely event he sues the infringer and obtains a court order requiring payment.

U.S. law has always recognized the fundamental right of a person to own property. Property rights are protected by the U.S. Constitution. Patents are property. The limited rights of inventors bestowed by patents also have a Constitutional basis.

Property rights, including patent rights, must and do yield to the rule of other laws. For example, the government can exercise the power of eminent domain to take away property including patents. Of course such a taking must be for a public purpose and requires payment of full value to the property owner. Courts have the power to extinguish patent rights by imposing compulsory license orders to punish a patentee for violating anti-trust laws by improper conduct involving the use of patents. However, U.S. patent law does not include compulsory license provisions. A U.S. patent gives an exclusive right to exclude others from the protected invention without exception save the limitation of the 17 term. We cannot believe that this Subcommittee, after careful consideration, will see fit at this time to make exceptions to this fundamental concept in U.S. patent law.

We see a second compelling reason for this Subcommittee not to fundamentally weaken U.S. patent law by adopting compulsory license amendments in this or any other bill. The Reagan Administration has made "fair trade" a major foreign policy initiative. A bipartisan Congress clearly supports this and is deeply involved in making the effort effective. An important part of the "fair trade"' initiative is the aggressive effort now underway throughout the world to encourage our trading partners to provide more complete protection of intellectual property rights.

Securing improved foreign patent laws is a critical component of U.S. negotiations in the "Uruguay Round" of GATT, in WIPO sponsored consideration of the Paris Convention Revisions and the "patent harmonization" committee of experts meetings, and in numerous bilateral situations. The United States Trade Representative (USTR) in a statement submitted to the House Judiciary Committee on February 19, 1986 has correctly concluded:

> Among the most troublesome practices in the patent area are: compulsory licensing rules; non-patentability of many important classes

> of products such as pharmaceuticals and chemical compounds; and patent terms that are unreasonably short.

A great strength of the U.S. negotiating position is that U.S. patent law does not contain these objectionable and weak features. The USTR can point to U.S. law as a model we recommend to the world. The USTR can correctly state that the U.S. provides strong patent protection for foreign inventions and has the right to expect that foreign countries should provide equally strong protection for U.S. inventions.

We do not doubt that the compulsory license provisions of S. 568 would compromise important U.S. interests in patent law related negotiations. On September 10, 1986, Secretary Baldrige wrote to Senator Mathis about these provisions then contained in S. 1543:

> The Administration cannot support these provisions as drafted. Compulsory licensing has no place in U.S. patent law. Inclusion of these features will undermine U.S. efforts to persuade other nations not to adopt them in their own laws or to limit their use. It will also undermine our efforts to make certain features of our patent law compatible with the laws of our major trading partners.
>
> For these reasons, the Administration urges the Committee to close a loophole for unfair foreign imports by adopting process patent protection without features that compromise the overriding integrity of intellectual property law worldwide. This is critical to the competitiveness of U.S. industry and I commend your attention to the problem.

AIPLA respectfully urges this Subcommittee, as has Secretary Baldrige, to carefully consider the domestic and foreign implications of these provisions of S. 568.

* * *

On behalf of the members of AIPLA, I thank the Subcommittee for allowing me the opportunity to testify at this hearing.

Senator DECONCINI. Thank you, Mr. Kline, and we appreciate your offer to work with us.

Mr. Witte?

**STATEMENT OF RICHARD C. WITTE, PROCTER & GAMBLE CO., ON BEHALF OF INTELLECTUAL PROPERTY OWNERS, INC., CHEMICAL MANUFACTURERS ASSOCIATION, AND NATIONAL ASSOCIATION OF MANUFACTURERS**

Mr. WITTE. Mr. Chairman, I thank you for this opportunity to discuss process patent legislation today.

I am here on behalf of three associations whose members include a large portion of the patent holders in the United States. The three are: the Intellectual Property Owners, Inc.; the Chemical Manufacturers Association; and the National Association of Manufacturers.

I am the chief patent counsel for the Procter & Gamble Co.

We have just a few comments on some of the limitations in the bills. All of the bills under consideration here limit the liability of importers, sellers, and users of products made by patented processes.

Infringers other than manufacturers—the actual practitioners of the processes—are liable only after they receive notice of infringement. This is fair. But we urge the subcommittee not to adopt the additional limitations on liability which are proposed in some of the bills, particularly unduly strict notice requirements.

We support S. 635. We also believe that S. 573 is a reasonably good bill.

Importers, sellers, and users should be held accountable for infringement after reasonable notice if the proposed legislation is to be effective in stopping infringing imports. They should have the same patent infringement responsibility that they have now under existing law.

Businesses have long been able to cope with their duty to avoid product patent infringement. They avoid problems by doing their homework to ensure freedom from patent infringement and/or use the almost universal patent indemnification clauses in supply contracts.

The same burden should be applicable to users and importers under the proposed new legislation. Importers and users at the current time must ensure that foreign-made products are safe and that they do what they are supposed to do.

Contrary to Mr. Engelberg's arguments, I believe that, under the new law, they could also check to ensure noninfringement of patents and/or get indemnity from their suppliers. I believe that the foreign manufacturers must accept this responsibility to ensure freedom from patent problems and/or indemnify if they want to do business and make profits from exporting products to the United States.

S. 568 contains limitations on the infringement liability of importers, sellers, and users. Many infringers would receive a limited license to continue infringing. We see no justification for allowing this. This type of license is not available to protect infringers from product patents.

Moreover, this limited license would remove the incentive for importers and industrial users to investigate patent rights before making business investments. It would remove their incentive to make inquiry of their foreign suppliers about the processes which are being used. It would also remove their incentive to arrange for proper indemnification clauses in supply contracts. In short, these limited licenses would make enforcement of process patents more difficult than the enforcement of product patent rights under existing law.

S. 568 also contains a request-for-disclosure procedure which shifts to the patent owner responsibility in advance of litigation for determining whether a competitor's activities might infringe. We urge that the request-for-disclosure concept not be adopted. We believe that it is unnecessary because all patents are on the public record for examination, because the infringer is in the best position to evaluate his own situation, and because the request for disclosure is hypothetical.

The best person to determine what patents might present problems is the foreign infringer. This is the unit most likely to come up with the right answer. This request for disclosure could well develop into a technical trap for the patentee which would unfairly cause the patentee to lose rights. It could also involve disclosure of sensitive business, legal, or technical information to competitors.

Also, S. 568 and S. 573 contain a special rule for starting liability for damages which we believe is unwarranted. It almost requires a patentee to prove his case before he can even plead it. The rule for damages in process patent cases should be the same as for product patent cases. This rule is a good-faith pleading to constitute notice rather than proof of a substantial likelihood.

In summary, we compliment the sponsors of the bills and the members of the subcommittee on their interest in strengthening patent rights. Such action could improve American competitiveness and increase jobs.

Thank you.

[Submissions of Mr. Witte follow:]

STATEMENT OF RICHARD C. WITTE

PROCTER AND GAMBLE COMPANY

ON BEHALF OF

INTELLECTUAL PROPERTY OWNERS, INC.

CHEMICAL MANUFACTURERS ASSOCIATION

NATIONAL ASSOCIATION OF MANUFACTURERS

ON S. 568, S. 573 AND S. 635

PROCESS PATENT LEGISLATION

Mr. Chairman and Members of the Subcommittee:

I am testifying on behalf of three associations whose members include a large portion of the patent holders in the United States: the Intellectual Property Owners, Inc. (IPO), the Chemical Manufacturers Association (CMA), and the National Association of Manufacturers (NAM). We welcome this opportunity to comment on the proposed process patent legislation.

IPO is an association of corporations, small businesses, universities, and individuals who own patents, trademarks and copyrights; CMA is a trade association whose member companies represent more than 90 percent of the productive capacity of basic industrial chemicals in the country; NAM is an association of more than 13,000 corporations, large and small, which employ 85 percent of all workers in manufacturing. I am vice president of IPO, a member of the Patent and Trademark Committee of CMA, and chairman of the Intellectual Property Task Force of NAM.

Need for Legislation

America's competitiveness can be strengthened by providing more effective legal protection for American technology. By protecting the owners of U.S. patents from free riders who have no R&D expenses, we can protect many thousands of jobs

in the United States in industries that manufacture for the U.S. market and export markets.

One way to improve patent protection is to close the loophole in U.S. patent law relating to process patents. Patent owners need the ability to sue for infringement in federal district courts when someone imports into the United States, or sells or uses in the United States, a product made abroad by a patented process. Under current law process patent owners cannot recover any monetary damages in this situation.

Major trading partners of the United States, including Japan, West Germany, France, and the United Kingdom, already have process protection in their patent laws. In most respects, the U.S. patent system is one of the best in the world, but the process patent loophole is an exception.

The U.S. government, with strong support from industry, recently has become more aggressive in attempting to influence other countries to upgrade their patent systems. Negotiations are now under way on intellectual property in the new round of GATT talks. It is an embarrassment that we lack adequate protection for process patents in our own law when we are urging strengthening of foreign laws.

The associations I am speaking for supported process patent legislation in principle in the last Congress. Today I would like to comment specifically on the three bills now pending before the Subcommittee -- S. 568, S. 573, and the Administration's proposal which is in several bills including S. 635. We believe S. 568, and to some extent S. 573, contain undesirable limitations on liability for infringement. We favor a bill along the lines of S. 635, assuming it is clear that it covers important processes for making chemical intermediates and biotechnology products.

Principles of Effective Patent Protection

To establish a framework for discussion, I would like to begin by reviewing the principles of effective patent protection. First is the principle that patents

should give the right to exclude others. U.S. patent law defines a patent as the right to exclude others from making, using or selling the invention. The right to exclude means the right to obtain an injunction against infringers. Federal courts have upheld exclusive patent rights worth many millions of dollars in cases involving patents covering products.

Many foreign patent systems, on the other hand, are riddled with "compulsory licensing" provisions, which are inconsistent with the concept of exclusivity. Under foreign systems, patent owners can be compelled to permit others to make, sell or use the invention in return for a so-called "reasonable royalty." The right to a government-controlled royalty is far less valuable than an exclusive right.

A second principle is that patent owners should be able to exclude not only manufacturers, but also sellers and users of patented inventions. Sellers and users -- which, among others, include importers, distributors, large retailers and large industrial users -- must be liable for infringement if patents are to be effectively enforced.

Businesses in the chain of distribution are entitled to indemnity from their suppliers when a product infringes a patent. The Uniform Commercial Code (UCC) in section 2-312(3) provides that a seller normally warrants against claims of patent and trademark infringement. In practice, parties usually put more specific indemnity or "hold harmless" clauses into their contracts. These clauses are tailored to the particular situation to place the ultimate responsibility for patent infringement on the seller or, if the parties agree, on the buyer, or some combination of the two.

A third principle is that patents should be enforceable without unnecessary burden and expense for the patent owner. Under U.S. patent law, and under U.S. copyright law as well, actual knowledge of infringement or intent to infringe generally is not required for an infringer to be liable. Infringement is not a question of guilt or innocence. The patent owner has no responsibility for

advising potential infringers of the scope of patent rights in advance of litigation.

Prospective infringers can rely on indemnity clauses and, if their investment and potential liability warrants, conduct patent searches and obtain legal opinions on the scope of existing patents before making investments. For both product patents and process patents, the primary way of finding out the status of patent rights is to conduct a search of the public records at the United States Patent and Trademark Office.

A final principle of effective patent systems is that patents need to be available in all fields of technology. Some countries limit or deny protection for certain subjects of inventions, including pharmaceuticals, but U.S. patent law covers all fields of technology. By denying or limiting patent protection in fields perceived to be most important, countries cut off the incentives for future technological advances in those fields.

The process patent legislation under consideration covers all fields, as it should. Although the debate over this legislation has focused on the pharmaceutical industry, it should be kept in mind that only a small percentage of the patents issued by the Patent and Trademark Office cover processes for manufacturing pharmaceuticals. Any limitations that are included in the bill will affect not only the pharmaceutical industry, but every other technology-based industry as well.

Liability of Importers, Sellers and Users

I would now like to turn to specific features of S. 568, S. 573, and S. 635.

All of the bills limit the liability of importers, sellers and users of products made by patented processes in one way: the bills make infringers other than manufacturers liable only after they receive notice of infringement. This requirement for actual notice was included in bills in the last Congress as well.

Under existing patent law, sellers and users of products covered by product patents are liable for infringement without actual notice, if the patent owner marks his own product with the patent number. Under existing law, manufacturers who use patented processes also are liable without notice.

We do not disagree with requiring actual notice for liability for process patent infringement by importers, sellers and users, but we urge the Subcommittee not to adopt any of the several additional limitations on liability which are proposed in the bills.

For example, S. 568 gives an exemption for retail sales for 18 months after notice, provided the retailer meets certain requirements. S. 568 also contains a number of limitations on the liability of importers and distributors, discussed later in this statement.

Large importers, sellers and users must be held accountable for infringement after notice if the proposed legislation is to be effective in stopping infringing imports. They should have the same responsibility that they have under existing law with respect to product patent infringement. Businesses have been able to cope with their responsibilities for avoiding product patent infringement for decades with little apparent difficulty.

It is importers, distributors, large retailers, and large industrial users that are of concern. Patent infringement suits against smaller retailers are almost nonexistent. Monetary damages based on the volume of sales by a small retailer would not begin to cover the cost of litigation. In a number of cases, however, patent owners have obtained relief from large retailers for patent infringement.

In preparing for this testimony, we examined the texts of several dozen indemnity clauses that have been used by patent owners and their suppliers and customers to assign responsibility for patent infringement. Such clauses are common in sales contracts in every major manufacturing industry. Typically the clauses not only indemnify purchasers for patent infringement damages, but obligate the manufacturer to defend lawsuits filed against purchasers. Clauses

sometimes obligate manufacturers to supply an alternative non-infringing product if the product contracted for turns out to be an infringing product. Clauses sometimes obligate manufacturers to take back infringing items in the possession of the purchaser.

We can see no reason why importers, sellers and users in this country cannot insist on such clauses in supply contracts with foreign manufacturers. If foreign manufacturers will not agree to the clauses, it may be an indication that they are infringing. If that is the case, passage of legislation with liability for importers, sellers and users will give incentives for them to find domestic suppliers, creating jobs in the United States.

Compulsory Licensing

Under S. 568, which is the bill that contains the most limitations on liability of importers, sellers and users, many infringers would receive a six month or eighteen month license to continue infringing after being notified of infringement. The six month license and the eighteen month license differ in scope.

The six month license is limited to units of the infringing product ordered before notice of infringement. The eighteen month license covers all products imported, used or sold by the infringer during the eighteen month period following notice of infringement. The eighteen month license becomes applicable wherever the patent owner elects not to comply with the "request for disclosure" procedure discussed later in this statement. By filing a lawsuit, a patent owner could recover a "reasonable royalty" for infringement during the six or eighteen month period.

We can see no justification for allowing either the six month or the eighteen month license. This type of license is not available to product patent infringers under existing law. The six or eighteen month license would remove the incentive for importers, distributors and industrial users to investigate the status of intellectual property rights before making business investments.

It would remove the incentive to make inquiry of foreign manufacturers about the processes being used. It would remove the incentive for importers, sellers and users even to arrange for indemnity clauses in their contracts with their suppliers. In short, it would leave the enforcement of process patent rights more difficult than the enforcement of product patent rights under existing law.

It would also be the first significant compulsory licensing requirement in U.S. patent law. We believe the six and eighteen month licenses would undercut current efforts to eliminate compulsory licensing from foreign patent laws. Compulsory licensing is invoked in many foreign countries whenever the patent owner fails to manufacture in that country. If the threat of compulsory licenses abroad could be eliminated, U.S. patent owners would be more likely to manufacture patented technology in the United States for foreign markets. Consequently we urge the Subcommittee not to adopt the six and eighteen month compulsory license of S. 568.

S. 573 contains a provision that gives the courts express equitable discretion to take care of transitional situations in which products are on hand or on order when the infringer receives notice of infringement. While this kind of transitional provision does not amount to compulsory licensing in our opinion, S. 573 could leave an opening for prospective infringers to stockpile large quantities of a product before receiving notice of infringement as a way to avoid an injunction. The proper scope of this provision should be considered carefully.

Request for Disclosure Procedure

S. 568 contains a request for disclosure procedure that shifts to the patent owner responsibility in advance of litigation for determining whether a competitor's activities might fall within the scope of a process patent. The bill establishes a procedure under which a competitor can make a written request to a party engaged in manufacturing a particular product to identify "all process patents owned or licensed to that party ... that could reasonably be asserted to be infringed." According to a draft Senate Judiciary Committee

report published on the predecessor bill at the end of the last Congress, patent owners also would have a perpetual duty to update lists of process patents identified pursuant to requests for disclosure.

We urge that the "request for disclosure" concept not be adopted. Although last year's draft committee report attempted to allay concerns about this procedure by suggesting that patent owners could err on the side of listing too many patents when in doubt, Federal courts have held patent owners to very strict standards of compliance with other duties to disclose information. Complex and expensive litigation has arisen concerning the duty of patent applicants and owners to disclose information to the Patent and Trademark Office under 37 C.F.R. §1.56. We believe the request for disclosure procedure of S. 568 would cause similar litigation.

Further, we believe there is no justification for putting a burden on patent owners to advise their competitors whether they might file a lawsuit in hypothetical situations. The expense of responding to requests for disclosure could be substantial. Patents cover not only the subject matter defined in the patent claims but also "equivalents" of the claimed subject matter. Patented processes often can be used to make several products. The patent owner may not be engaged in manufacturing precisely the same product that the competitor plans to manufacture.

Even if the information requested was provided to a competitor, the competitor still would have to find out what process was being used by the foreign supplier in order to be confident that infringement would not occur. The main way to find out what patent rights exist is to search the publicly available records at the U.S. Patent and Trademark Office. Process patent records can be searched in the same way product patent records are searched. We know of no evidence that importers, sellers and users are finding the burdens of avoiding product patent infringement an unreasonable business expense.

Other Comments

S. 568 contains a special rule for starting liability for damages, which we

believe is unwarranted. It requires a notice of infringement "sufficient to establish that there is a substantial likelihood that the product was made by the infringing process."

S. 573 also has a special rule on damages, which, while less restrictive than the "substantial likelihood" requirement of S. 568, could cause unnecessary litigation. S. 573 requires "the reasons for belief that such process or processes were used in the production." The rule for starting of liability for damages in process patent cases, when the infringer has been notified of infringement, should be the same as for product cases. S. 635 wisely avoids establishing any special rule for process patents on this point.

All three of the bills limit their coverage to products that have not been "materially changed by subsequent processes" after being manufactured by the patented process. We believe this provision needs clarification. It is unclear whether the bills would protect patented chemical intermediates that are then used to make an end product through routine chemical processes. The bills should protect such intermediates. The bills also could be construed not to cover certain biotechnology processes. For example, a patented process may be used to prepare a DNA molecule comprising a specific genetic sequence, and then unpatented processes can be used to insert the molecule into other materials to make a final product. The bills should cover the final product. We note that one bill in the House, H.R. 380, omits the "materially changed" language.

We are strongly opposed to incorporating any of the limitations on liability from the pending process patent bills into the bills now pending in Congress to amend section 337 of the Tariff Act of 1930. At the end of the last Congress, proposals were made to limit temporary exclusion orders under section 337 and to introduce the request for disclosure procedure into section 337. We favor the pending bills to strengthen section 337 in their present form, but believe there would be little support for them if they contained the limitations on relief that are in S. 568.

Conclusion

We compliment the sponsors of the bills and the members of the Subcommittee on their interest in legislation to strengthen patent rights and improve American competitiveness.

Any legislation that is enacted, however, should insure effective remedies against offshore manufacturing by using patented processes. The legislation also should be consistent with principles of effective intellectual property protection now being urged on other countries by the U.S. government and U.S. industry. The ground rules for enforcing process patent rights should not differ significantly from the established rules for enforcing product patent rights.

IPO, CMA and NAM appreciate this opportunity to present their views. I will be glad to answer any questions.

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May 8, 1987

The Honorable Dennis DeConcini
Chairman, Judiciary Subcommittee
on Patents, Copyrights & Trademarks
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

During my testimony on process patent legislation on April 22, you asked about objections to the "request for disclosure" procedure in S. 568. I am writing on behalf of Intellectual Property Owners, Inc. (IPO) to explain this point further.

We believe the request for disclosure procedure should not be adopted, because:

- It would be burdensome and expensive for patent owners to compile a listing of process patents in response to a request for disclosure; and
- The listing would not give the requester enough information to assess the likelihood of infringement.

Burden and Expense for Patent Owners

In essence, the request for disclose procedure in S. 568 requires a U.S. patent owner who is then engaged in the manufacture of a product to provide a listing of all of its process patents "that could reasonably be asserted to be infringed" if parties in the U.S. imported, used or sold that product.

To respond to a request for disclosure, a patent owner would have to try to imagine all the processes which might be used for making a particular product. A patent owner is not in a position to know what process a competitor or its supplier is planning to use.

When a conventional patent search is conducted to determine whether a process would infringe existing patents, the party conducting the search, usually a manufacturer who wants to avoid charges of infringement, knows the identity of the potentially infringing process. If one knows the steps in the process being used (steps in a patented process could be, for example, heating, combining, stirring, cooling, etc.), it is relatively simple to compare those steps with the process steps claimed in patents in the public

records at the U.S. Patent and Trademark Office. Without knowledge of the identity of the potentially infringing process, however, anyone attempting to say what process patents could be asserted against an importer, user or seller of a product is engaging in a speculative exercise.

In chemical and pharmaceutical manufacturing, an end product may be manufactured by taking a starting material and using a first process to convert it to an intermediate material, using a second process to convert the first intermediate material to another intermediate material, and so on until the end product is reached. A patent may cover only the steps for making one intermediate. To be sure of listing all relevant process patents, the patent owner would have to analyze what combinations of intermediates could lead to the end product.

Not all of the products that can be manufactured by using a process are necessarily known when a patent is obtained on the process. This means a process patent owner, responding to a request for disclosure, would need to investigate information other than that contained in published patent documents.

Also, the patent owner would have to try to guess whether its patents would cover different but equivalent processes under the patent law doctrine known as the "doctrine of equivalents". It is impossible to foresee all of the equivalents that could be covered by a patent.

Requests for disclosure could become traps for unwary patent owners who would be tempted to take the easy route of listing too many of their patents when in doubt about which ones to list. This could become a subject for litigation during infringement suits.

The request for disclosure idea in some respects resembles the requirement for disclosing information to the Patent and Trademark Office under 37 CFR 1.56. Since section 1.56 was adopted in 1977, disclosure issues have been litigated in hundreds of cases. Owners have had to defend charges of disclosing too much information, as well as too little information. By analogy, we believe infringers would seek to penalize owners for listing too many patents in responses to requests for disclosure.

We are also concerned about requiring patent owners to make available to competitors the information they already possess about the strength and coverage of their patents. Traditionally this kind of strategic information is closely held until the time comes to make a decision whether to begin litigation to enforce patent rights. In addition, S. 568 as currently drafted calls for providing information about patents licensed to the company as well as those owned by the company. Information about patent licenses normally is not public.

The paperwork burdens involved in complying with requests for disclosure would be burdensome too. A patent owner could receive numerous identical requests from businesses at all levels in the chain of distribution.

Further, according to the draft committee report published on last year's predecessor to S. 568, patent owners would have a perpetual duty to update listings when they obtained new process patents.

To cope with the problems discussed above, patent owners would be compelled to spend significant amounts of time deciding which patents to list. The question, then, should be whether the expense is justified by the value of the listing.

Limited Value of Listings to Requesters

Once the requester received a listing of patents from the patent owner, what would be its value? The listing would not tell the requester anything about infringement unless the requester knew the process being used by the foreign manufacturer.

If the requester knew the process being used by the foreign manufacturer and obtained a listing, the requester still would be unable to evaluate the likelihood of infringement, because the listing would not tell the requester about patents covering the process owned by firms who were not then engaged in making the product. Frequently companies own patents relating to technology they have not commercialized.

It has been argued that a foreign manufacturer who is unwilling to indemnify customers for infringement of all process patents would nevertheless be willing to indemnify against infringement of specific process patents listed in response to a request for disclosure. It seems unlikely to us that this would be true in many cases. If the manufacturer is unwilling to do a patent search and indemnify against infringement of all process patents, the manufacturer likely would unwilling to go to the trouble of analyzing a listing of selected patents. Analysis of a listing could be as expensive as a patent search.

Even if a manufacturer was willing to indemnify for infringement of listed patents, that would not be complete protection for the party who requested the listing, because, as noted above, patents might be owned by parties who were not manufacturing. A prudent business person would insist on a general indemnity clause that would provide reimbursement for damages resulting from infringement of all patents.

Indeed, indemnity clauses obtained in the United States often go beyond reimbursing for infringement. They obligate suppliers to defend lawsuits filed against customers and to supply alternative non-infringing products if the product contracted for turns out to be an infringing product. Clauses sometimes even obligate suppliers to take back infringing items in the possession of the customer.

Reputable U.S. manufacturers consider patent indemnification clauses a routine cost of doing business. We believe foreign manufacturers should be willing to indemnify customers for all patent infringement too.

Alternative to Request for Disclosure

The principal objective of the proposed legislation is to deter foreign manufacturers from using patented processes to make products that are imported into the United States. We would not object to a reasonable limitation on liability for importers, users or sellers of such products who demonstrate that they have taken steps to help insure that the foreign manufacturer is not using a U.S. patented process.

For instance, a party in the United States could enter a contract with a foreign manufacturer in which the manufacturer would certify that it was not manufacturing by using any process patented in the United States, and that it would make available information about the process being used if the party in the United States was sued for patent infringement. This type of contractual provision could be taken into account in deciding the extent of liability for importers, users and sellers who were sued for infringement.

Treating this type of contract as evidence of a good faith effort to avoid infringement should help deter foreign manufacturers from using patented processes. We believe the request for disclosure procedure, however, should be omitted from any definition of good faith efforts to avoid infringement. The request for disclosure procedure would do very little to deter foreign manufacturers, but would impose substantial burdens and expense on patent owners.

Thank you again for the opportunity to present our views, and for your efforts to fashion a bill acceptable to all interested parties. We would appreciate it if this letter can be included in the hearing record.

Sincerely,

Richard C. Witte
Vice President

cc: Hon. Orrin G. Hatch
Hon. Frank R. Lautenberg

Senator DECONCINI. Thank you, Mr. Witte.
Mr. Tramontine?

## STATEMENT OF JOHN O. TRAMONTINE, THE NEW YORK PATENT, TRADEMARK AND COPYRIGHT LAW ASSOCIATION

Mr. TRAMONTINE. Thank you, Mr. Chairman.

I am appearing here today on behalf of the New York Patent, Trademark and Copyright Law Association. We have over 1,000 members and are the largest regional patent law association and probably have the greatest concentration of the litigators, namely, the people that enforce patents.

Our association has a problem with all three bills. Although all of the bills are described as being bills to protect patent owners from importation into the United States of goods made overseas by use of U.S.-patented processes, none of the bills are so limited. They are not limited to goods made overseas. They include goods made in this country by domestic manufacturers.

For the first time, liability gets extended to all persons who use or sell products obtained from a U.S. manufacturer, even though there is no patent on the product.

Now, there has been no attempt to marshal any justification for so changing our laws regarding goods made here in the United States. We believe that the laudable purposes of the bills—namely, to put ourselves on an equal footing with our major trading partners who have similar patent statutes on process patents—can be accomplished if we extend the liability only to the person that imports the product or makes the first sale in the United States of the product.

This would accomplish putting ourselves on equal footing for purposes of export and import trade. It would not change our domestic laws applied to domestic manufacturers because the domestic manufacturer would be the person charged with infringing the process patent and would also be the person who would make the first sale in the United States.

One advantage for U.S. manufacturers, if we so limited liability to first sale, would be that a consuming corporation here in the United States, in purchasing a product, would have to have an indemnification from a foreign supplier to indemnify against potential liabilities on process patents. But if he purchased from a U.S. manufacturer, no such indemnification would be needed. That, I believe, would give an advantage to domestic manufacturers.

Also, by limiting it to the importation or first sale, we believe that many of the disputes that I have heard here today regarding notice and limitations on liability are no longer necessary because we are not now dealing with the chain of distribution after it comes into the United States and after the importation and first sale.

Mr. Chairman, I have two final points I would like to make, and they are litigator's points, and they have to do with, first of all, the presumption that appears in all three of the bills.

The presumption, like all presumptions, should be concerned with the burden of going forward with the evidence, not the burden of proof. All of the bills mix those two things up. They talk about a

presumption, but then they go on to talk about the burden of establishing something, and that is the burden of proof.

The purpose, namely, to put the onus on the alleged infringer where the patent owner cannot, although he has tried, find out how the product was made, could be accomplished by the presumption and the burden of going forward with the evidence. To go past that and put the burden of proof on the infringer to prove there is no infringement is unnecessary and, I think, unwarranted under our jurisprudence on patent infringement.

The other point is, on the presumption—I am still there—one bill, I believe yours, Mr. Chairman, talks about likelihood. This is for the presumption. "Substantial likelihood exists that the product was produced by the patented process." This is before the presumption would be applied. Senator Lautenberg's bill has similar language, but it is a little higher. It says, "a high degree of probability exists."

The burden of proof on patent infringement is preponderance of the evidence, which, as most of us know, means proof sufficient that a fact is more likely to be true than not true.

When I look at what is being required to raise the presumption, it almost seems I have already proven my case and I don't need the presumption. If there is a substantial likelihood that something exists, I think I have carried my burden of proof on infringement by preponderance of the evidence.

The final point from the litigator's standpoint has to do with the claim that the innocent retailer needs statutory protection for 6 to 18 months so that he can get rid of his inventory. There is nothing that is going to stop him from getting rid of his inventory other than an injunction from a court and, I can assure you, no patent owner can get an injunction out of a court in 6 months or a year from the date he actually files a lawsuit.

He is only going to get that after trial and posttrial briefings; then there are going to be motions to stay pending appeal; and throughout all that time period, the inventory is already gone; it is out the door. I don't know of a single case where an injunction came down in less than 1 year after suit was commenced.

So this notion that statutory protection is needed to get rid of inventory is nonsense, in all candor.

Thank you, Mr. Chairman.

[Statement of Mr. Tramontine follows:]

# Prepared Statement of John O. Tramontine on Behalf of the New York Patent, Trademark and Copyright Law Association

## Introduction

The New York Patent, Trademark and Copyright Law Association strongly supports the enactment of legislation extending the current protection afforded by U. S. process patents so that our country's exports and imports will be on equal legal footing with those of our major industrial trading partners. But the problem with all three of these bills is that they go far beyond this laudable purpose and change our laws in a way that will adversely and unnecessarily affect our own domestic manufacturing industries.

These bills are described as bills "to protect patent owners from importation into the United States of goods made overseas by use of a U. S. patented process." But none of these bills are limited to goods made overseas. They include goods made in this country by domestic manufacturers and then extend liability for the first time to all persons who use or sell the product obtained from our U. S. manufacturers, notwithstanding that there is no U. S. patent on the product. There has been no attempt to marshal any justification for so changing our laws regarding goods made here in the United States.

## Summary of Suggested Modifications

We suggest that these bills should be modified so that they extend liability only to persons who import or make the first sale in the United States of the product produced by the patented process. This would accomplish the legitimate purpose of these bills by putting us on

equal legal footing with our major industrial trading partners for purposes of our export and import trade. But because the domestic manufacturer (who is infringing the patented process) also will be the person who makes the first sale in the United States, there will be no change in substance of our current laws regarding goods made in the United States.

With the extension of liability so constrained to accomplish its legitimate purpose, most of the other proposed provisions, e.g., the notice and limitation on liability provisions, become unnecessary. A presumption, shifting the burden of going forward with the evidence (but not the burden of proof), is needed where the patent owner has been unable through discovery to determine the process actually used to make the product. The presumption provisions of these bills unfortunately speak of both the presumption (burden of going forward with the evidence) and the burden of proof (burden of "establishing" or persuasion). The presumption or "burden of proof" in foreign laws equates to our burden of going forward with the evidence, not to our burden of proof.

Background

Many, if not most, of our industrial trading partners (Groub B countries) have process patent laws similar to those proposed in these bills. But they have them for reasons that have no application to the enforcement of U. S. process patents against our domestic manufacturers. The main reason for such process patent laws in foreign countries is that they do not have our discovery procedure in the enforcement of patent rights. Thus, the patent owners are unable through discovery in foreign Courts to

determine the process used to make the product. We suffer no such disability in enforcing U. S. process patents against domestic manufacturers. Furthermore, in many foreign countries certain types of products cannot be patented, such as chemical and pharmaceutical products, food products and products of biotechnology. We have no such restrictions under our laws.

Thus, we have no need for such laws with regard to our domestic manufacture and domestic marketing. But notwithstanding that these foreign process patent laws came about for reasons that do not apply in this country, they have impacted the exports of our domestic manufacturers and parity for that reason is required.

Adverse Impact On Domestic Manufacturers

Under current law only the domestic manufacturer is liable for infringing a U. S. process patent. But under the proposed bills, each person who uses or resells a product purchased from that domestic manufacturer will be liable for infringement of that process patent, notwithstanding that there is no U. S. patent on the product.

If liability for infringement is not cut off at the first sale, domestic manufacturers may be forced to disclose their secret process technology to a series of users and sellers to reassure them, or allow them to make their own determination, that they are not indirect infringers of any existing process patents. Furthermore, the domestic manufacturer and each person in the chain of distribution would be warranting, under Section 2-312(3) of the Uniform Commercial Code, that the product it delivers does not infringe a U. S. patent, which would now for the first time include process patents.

For an example, assume that Company A holds a patent on a process for making rubber. Company B (a domestic manufacturer) makes rubber which it sells to Goodyear, who sells its tires to General Motors, who sells its cars to consumers. Under the proposed bills, charges of infringement of the process patent could be made against every person in that chain. Those persons may be deemed joint tortfeasors (infringers) with joint and several liability.

If the patentee chooses to sue Goodyear, and the value of the tire greatly exceeds the value of the rubber raw material, Company B (who will be required, as a practical matter, to indemnify Goodyear) may face damage liability far in excess of the revenue it derives from selling the rubber.

Objections To Our Suggested Modifications

Those that oppose our suggested modifications do so on two main grounds -- (1) that it would not meet the need for this legislation and (2) that the person who ultimately uses the imported product could be insulated from liability by using one or more intermediaries who would import and make the first sale in the United States.

First on the need for this legislation, it has been said that process patentees require more effective enforcement means against infringement by domestic manufacturers than merely suing those who actually use the patented process. We are not aware of any facts that would support this view, nor have any been advanced. It also has been said that use in a foreign country of a process that is patented in the United States and importation into the United States of the product is an impermissible circumvention of the patentee's exclusionary rights in the

process. But the concept that a patent can only be infringed by acts within the country that issued the patent is elemental in the patent laws of every country, including our own.

Turning to the second point, the use of intermediaries to import and make the first U. S. sale would not insulate the ultimate domestic user of the imported product from liability. Under our existing laws, one who actively induces an infringement of a patent is liable as an infringer. 35 U.S.C. § 271(b). Thus, the ultimate domestic user who with knowledge of the U. S. process patent places a purchase order and thereby actively induces importation and first sale of the product would be liable as an infringer.

Also, by application of existing law, a foreign manufacturer who with knowledge of the U. S. process patent sells the product for importation into the United States would be liable as an active inducer of infringement. See, for example, Honeywell, Inc. v. Metz Apparatewerke, 509 F.2d 1137 (7 Cir. 1965), Engineered Sports Products v. Brunswick Corp., 362 F.Supp. 722 (D.Utah 1973) and Hauni Werke Koerber & Co., K.G. v. Molins Ltd., 183 USPQ 168 (E.D.Va. 1974). Thus the holder of a U. S. process patent could have a remedy directly against the foreign manufacturer.

Conclusion

Our Association believes that these bills can be improved by a more careful balancing of the needs of process patentees and the burdens imposed on domestic manufacturers and retailers. That balance can be achieved by defining, as acts of infringement, the importation into the United States, or the first sale in the United States, of a product made by a patented process.

Senator DECONCINI. Thank you, Mr. Tramontine.

Mr. Kline and Mr. Witte, the associations that you represent and some of the clients we know that you represent, seem to be very confident that foreign suppliers to an independent generic company will be willing to disclose their actual method of production. How do you come to that conclusion? Is that based on experience? Do you get that information from foreign suppliers easily?

Mr. KLINE. I am not sure I understand your question, Mr. Chairman.

Senator DECONCINI. Well, let me ask, if you request a foreign supplier for the information regarding their product, do they give it to you willingly?

Mr. KLINE. As to how this product was made?

Senator DECONCINI. Yes, sir.

Mr. KLINE. I am not sure that they would willingly give it to you. On the other hand, if there is a concern on the part of the U.S. purchaser that there is a potential here for infringement litigation, he can go to the manufacturer and ask whether he is willing to disclose that or get the indemnities which will give him the assurance that, if he is not willing to disclose it, that the manufacturer will be standing behind him.

Senator DECONCINI. What is your experience in trying to get that information from foreign suppliers?

Mr. KLINE. I cannot say that I have any personal experience in that regard.

Senator DECONCINI. Mr. Witte, do you?

Mr. WITTE. I have no personal experience. I understand that foreign manufacturers who make drugs have to tell the FDA how the drugs are made, but that information may or may not be available to the actual generic who sells the imported drugs. So the information is here, but it is often held in secret.

But it seems to me that if the foreign manufacturer wants to make money from doing business in the United States, and if this whole concept of process patent infringement is to mean anything, then that would be a price that they would have to pay, either that or indemnify. If the secret is so dear to them that they don't want to even disclose it in confidence under a contractual trade secret obligation, if that is so important to them, then, as Mr. Kline says, all they have to do is agree to indemnify.

Senator DECONCINI. Mr. Witte, you mentioned the objections of disclosure provision in the bill because you would be doing somebody else's work and that you might end up disclosing some confidential information.

Patent is public information, is it not? And how onerous is that for a patent owner to have to just give a list when requested of what patents they own? I just do not see how this is going to disclose anything of a confidential nature when it is public information if you research it.

Mr. WITTE. Well, in some situations, it may be very easy. If there is an obvious patent that is one that is very important to the manufacturer, and it may be well known, it would be onerous. But that information is just as readily available to the person who is the object of that provision in the S. 568.

What I am mostly concerned about is a situation where a company has, say, half a dozen or more process patents, and it may be a secret as to which one the U.S. manufacturer actually uses in their own manufacture. Now, it may be that the requirements of this disclosure would be satisfied by disclosing all six.

Senator DECONCINI. Yes. Couldn't you just disclose them all in that case? What if you had 200? I just do not see the argument from the objection that you and Mr. Kline have raised here, why that is any great burden. It almost seems to me it would be a protection for your clients because you are getting it out there early on instead of having to wait for it to pop up and then be confronted with the problem. Maybe you can explain to me why this is such a great burden.

Mr. WITTE. Well, if it is to the U.S. manufacturer's best interest, then it ought to be a voluntary thing, that we say we want you to help us do our homework to make sure we don't get in trouble with your patents, so would you mind telling us?

Senator DECONCINI. Yes.

Mr. WITTE. Now, it ought to be up to the choice of the U.S. manufacturer as to whether they want that help or not, but to be forced to do it——

Senator DECONCINI. What is the problem of forcing them to do it?

Mr. WITTE. Well, my main concern is that it is just an extra technicality in patent litigation that will be a trap for the U.S. patent holder to somehow or another lose his U.S. rights. It would be another point litigated.

Senator DECONCINI. Well, that "somehow or another" does not help me.

Mr. Kline, can you give me something to hang a hat on here that would be substantial or an experience that you could lose something just by giving notice?

Mr. KLINE. Well, Mr. Chairman, I cannot give you any actual experience, but it seems to me that, as Mr. Witte has said, there may be a series of patents that the U.S. patent owner holds, that if he is required to reveal all of the patents that he has which may be pertinent to the operation of his process to produce that product, in so giving that list of patents, he may be revealing some confidential information that he has with regard to what he, himself, may be doing that——

Senator DECONCINI. Aren't those patents public?

Mr. KLINE. The patents themselves are public, but as to which of his patents may be pertinent to the operation of the process, that, in and of itself, is not a matter of public knowledge.

Now, to go back to—I think you mentioned, well, if he were to just list, say, 200 patents that he owns, I am not so sure that, while that might get away from the concern about revealing competitive or confidential information, whether that would serve the purpose of the proposers of that particular language.

Senator DECONCINI. Yes.

Well, Mr. Engelberg pointed out the fact that they asked for a patent from Lilly or somebody and they got 300 back. I just find it awfully hard to see how that is any great burden, any more than you do not have to do it today.

Mr. KLINE. Yes.

Senator DECONCINI. Whenever you have to go through another exercise, I realize that is one more person to have to assign to the position and have to keep records or put it on the computer so you can pull it up without disclosing the confidential information.

But I think Mr. Witte indicated that you would be disclosing—may be disclosing—confidential information. I don't see how that is confidential when it is already at the Patent Office for everybody to come look at if they want to go search it. What we are trying to do is expedite and to help once that notice is given.

Mr. KLINE. I think it is not the point, Mr. Chairman, that you are disclosing—it would not be disclosing confidential information, which information is already in the public document; that is, the patent.

Senator DECONCINI. Right.

Mr. KLINE. It would be the confidential aspect of specifically identifying that this patent is one that you might be operating yourself, and therefore you are including it in the list, and that may be information that, at that particular time, you do not want to reveal.

Senator DECONCINI. Mr. Tramontine, does your association oppose that, too, the request for disclosure?

Mr. TRAMONTINE. We do not have a position on that. The problem I can envision is, it may not be a simple matter to say whether a given patent relates to the patent owner's product. In many lawsuits, there are issues as to whether the patent that is being asserted covers the patent owner's product so that the commercial success of the patent owner's product can be attributed to this patent.

Those are sometimes difficult legal issues, and it might be calling for a fairly complex legal opinion. But I think that would be the rare case.

Senator DECONCINI. You mentioned the time problem, Mr. Tramontine, of getting an injunction. How many of the complaints or cases actually go that far, to trial? Is it 10 percent or 20 percent? How many are not settled somewhere along there?

Mr. TRAMONTINE. The settlement ratio used to be 70, 80 percent, up in that area, but the settlement ratio has gone down. I would say that—this is my own personal gut reaction—50-50 cases are going to trial.

Senator DECONCINI. Fifty percent go to trial?

Mr. TRAMONTINE. Yes.

Senator DECONCINI. All right, gentlemen, thank you very much.

Mr. Kline and Mr. Witte, I appreciate—particularly Mr. Kline—your willingness to work with us on this. Having discussed it with you, I understand your strong feelings here. We would like to not do irreparable harm to your clients and your associations' positions, but we would like to work with you on this bill. If you can make yourself available, we will make ourselves available. Thank you.

Mr. KLINE. Thank you, Mr. Chairman.

Senator DECONCINI. The committee will stand in recess, subject to call of the Chair.

Thank you very much.

[Whereupon, at 11:39 a.m., the subcommittee recessed, to reconvene at the call of the Chair.]

# APPENDIX

## Additional Statements

STATEMENT OF THE
AMERICAN TEXTILE MANUFACTURERS INSTITUTE

BEFORE
SENATE JUDICIARY SUBCOMMITTEE ON
PATENTS, COPYRIGHTS AND TRADEMARKS

April 22, 1987

Mr. Chairman, we appreciate the opportunity to submit this statement for the printed record of hearings on process patent protection legislation.

The American Textile Manufacturers Institute (ATMI) is the central trade association of the American textile industry, representing about 85 percent of the domestic industry for the spinning, weaving, knitting and finishing of wool, cotton, silk and man-made fibers. ATMI provides governmental, economic, international trade, occupational safety and health, statistical, public relations and other services to the industry. This industry represents a major industrial segment of the nation's economy with approximately 700,000 employees. Forty-seven percent are women and 23 percent are minorities, both figures being well above the national average for manufacturing.

At the outset, Mr. Chairman, ATMI supports process patent legislation. In the case of a process patent, there is no effective way by which a U. S. patentee can prevent a firm from duplicating the protected process overseas and then selling the product of that process in the U. S. The proposed legislation would protect American process patents from infringement abroad if the infringing product is shipped back to the U. S. just as those patents are

presently protected from infringement in this country. The legislation gives patent owners the right to sue for damages and seek an injunction in federal district court when their patents are infringed. At the same time, it places certain limitations on damages in cases of innocent (but not willful) infringement.

The American Textile industry is regarded today as the most efficient and modern in the world, and our government must protect the results of our industry's research and development -- the resources which have produced our superior efficiency. We cannot afford to allow anticompetitive practices such as patent infringement to further undermine our industrial base which has substantially eroded as a consequence of the import deluge over the last six years.

We recognize that Section 337 of the Tariff Act of 1930 provides for the exclusion of imports in cases of unfair competition or unlawful acts. A complaining party, however, must demonstrate that the imports threaten an efficient and economically operated domestic industry with substantial injury. Because the U. S. textile industry has been inundated with imports, it is very difficult to prove injury as a result of patent infringement. Consequently, ATMI also supports legislation amending Section 337 of the Tariff Act which would eliminate the requirement to prove "injury" in intellectual property cases and the "efficiently and economically operated" test requirement.

Most importantly, however, we support efforts of the subcommittee to preclude a copier from being able to circumvent legitimate rights flowing from a process patent simply by practicing the process in a foreign country. It is for these reasons we support process patent legislation. We believe we can continue to maintain some form of competitive edge over our foreign counterparts if U. S. patent owners are given the protection provided by the legislation that you are considering. Therefore, we urge the adoption by the subcommittee of this legislation.

AMERICAN BAR ASSOCIATION
GOVERNMENTAL AFFAIRS OFFICE • 1800 M STREET, N.W. • WASHINGTON, D.C. 20036 • (202) 331-2200

STATEMENT OF

WILLIAM MARSHALL LEE, CHAIRMAN

SECTION OF PATENT, TRADEMARK AND COPYRIGHT LAW

AMERICAN BAR ASSOCIATION

submitted to the

SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS

of the

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

on behalf of the

AMERICAN BAR ASSOCIATION

PROCESS PATENT LEGISLATION

S.539, S.568 and S.573

APRIL 22, 1987

I am William Marshall Lee, Chairman of the Section of Patent, Trademark and Copyright Law of the American Bar Association. This Statement as to process patent legislation is on behalf of the American Bar Association.

As a preface to this Statement it seems appropriate during this year of the Bicentennial of the U.S. Constitution to reiterate that the patent laws have been enacted and maintained by the Congress under the express power granted under Article I, Section 8, Clause 8 of the Constitution.

The patent system has well served the national interest since enactment of the first patent laws in 1790. The patent system has continued its encouragement of invention and innovation, and the nation has continued to enjoy their fruits: more jobs, new industries, and a flow of new products. An important function of the patent system has been to encourage investment-based risk, without which entrepreneurs and industry could not thrive as they have since our Founding Fathers wisely provided the Constitutional basis for patents.

Nevertheless, the patent laws in the U.S. need constant surveillance in order that they may continue to serve the nation in the future as admirably as they have in the past. This is particularly important in today's world in which the position of the United States as the pre-eminent industrialized nation is being increasingly challenged by other industrialized nations.

I applaud the initiatives already taken by the Subcommittee in the important effort to improve the U.S. patent laws so that they may more effectively serve the national interest. One of the most important is the effort to obtain enactment of process patent legislation, which is presently proposed in several different forms, including S.539, S.573 and S.568.

A vexing problem plaguing U.S. industry has been the lack of protection in the United States against importation of products made abroad which if made in the United States would infringe a U.S. process patent. Such protection is part of the patent laws of most of the major industrialized countries of the world. The lack of such protection adversely impacts on jobs in the United States.

Many of today's significant inventions involve new processes used to make existing - - and, therefore, unpatentable - - products. This was the situation, for example, in the case of United States v. Studiengesellschaft Kohle, GmbH., 670 F.2d 1122 (D.C. Cir. 1981), where the end product aluminum tri-alkyls were already known, but a new, patented process for making them revolutionized the industry. The importation of

products, such as the tri-alkyls, produced offshore by a U.S. patented process may be actionable in this country in certain circumstances as an unfair method of competition before the U.S. International Trade Commission under 19 U.S.C. §1337 and §1337a. However, as noted in Enka B.V. v. E.I. Dupont, etc., 519 F. Supp. 356 (D. Del. 1981), this statute does not extend the reach of the patent laws to cover such situations (i.d. at 362, note 8).

More specifically, process patent protection under current United States law extends only to activities in this country. As a result, an unpatented product made offshore by a patented process can be sold here without comprising an infringement. In contrast, the domestic patent law of other major countries would prevent similar importation into those countries by a United States manufacturer. For example, the European Patent Convention states: "If the subject matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process." Convention on the Grant of European Patents, Art. 64(2). If the product produced by the patented process is itself novel, the defendant is burdened in many of these countries with proving that this product was not produced by that process.

The U.S. Patent and Trademark Office has recommended amendments to 35 U.S.C. to close this gap in United States patent protection. The American Bar Association supports these efforts in principle inasmuch as it is felt that such legislation is important to enable patentees and holders of process patents to obtain the full benefit from their patent rights.

For a number of years the Section of Patent, Trademark and Copyright Law has advocated enactment of legislation which would provide protection for U.S. industry against products made abroad which would infringe U.S. process patents if produced in the U.S. About three years ago concern was raised by the U.S. Trade Representative that such legislation could raise problems under Article IV of the General Agreement and Tariffs and Trade (GATT) unless the legislation would protect against infringement by products made domestically as well as by products made abroad. Subsequently, in response to this GATT concern, the Section broadened its position to favor legislation which would provide protection against products produced by a process which would infringe a U.S. process patent regardless of whether the products are made domestically or abroad.

Opposition to such proposed legislation was voiced by the generic drug

manufacturers on the ground that existing commercial activities would be jeoopardized by the legislation in that products protected in this country only by a process patent might be excluded from importation. While there is good reason to believe this is not a frequent or serious problem, either because few products are dominated only by process patents or because most drugs or other chemicals can also be made by noninfringing processes, S.1543, introduced by Senator Mathias and others in the 99th Congress, attempted to meet the concern by providing an equitable exemption from infringement for products already imported or for which substantial preparation was made, analogous to the provision of 35 U.S.C. 252 providing for intervening rights in the case of a broadened reissue patent.

In 1986 the American Bar Association House of Delegates adopted a resolution favoring legislation which would establish protection against infringement of a U.S. process patent whether the infringing product is produced domestically or abroad. In pertinent part this ABA resolution is as follows:

> "BE IT RESOLVED, That the American Bar Association
>
> A. Supports in principle the enactment of legislation which (a) would establish that whoever without authority uses or sells within, or imports into, the United States during the term of a United States process patent a product produced by such patented process, infringes the process patent, and (b) would create a rebuttable presumption, in actions based on such use, sale or importation, that a product was produced by the patented process, if the court finds (1) that a substantial likelihood exists that the product was produced by the patented process and (2) that the claimant has exhausted all reasonably available means through discovery or otherwise but had been unable to determine, from the information provided by the manufacturer of the product, the process actually used in the production of the product; provided, however, that the legislation shall further provide that (i) no damages for infringement shall be recovered based on such use, sale or importation except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages shall be recovered only for infringement occurring after such notice, and (ii) the rebuttable presumption shall not apply if, at the time of commencement of the action, the manufacturer of the product produced by the patented process is either subject to the jurisdiction of a United States District Court in which venue as to such manufacturer can be established under 28 U.S.C. §1400(b), or consents to such jurisdiction in the District Court in which the action has been brought;"

Subsequently, the Section studied the matter of meeting the concerns of the generic drug manufacturers and now favors a "grandfather" provision which would continue to allow a person to use, sell or import products which on a stated and fixed date were already imported for sale or use in this country, or for which substantial preparation for import for sale or use had been made. The views in this paragraph

with respect to a proposed "grandfather" provision are being presented only on behalf of the Section of Patent, Trademark and Copyright Law and have not been approved by the House of Delegates or the Board of Governors of the American Bar Association, and should not be construed as representing the position of the ABA. It is believed that enactment of process patent legislation in accordance with the 1986 ABA resolution, with a "grandfather" clause, would provide the necessary protection for U.S. manufacturers and at the same time would achieve an equitable balance to meet the concerns of generic drug manufacturers and others. Of the three pending bills, only S.568 contains a grandfather clause. All three bills contain a shift of burden of proof provision.

Anyone faced with the task of proving "infringement" of a process patented in the U.S. by a product imported from a foreign country where discovery is unavailable would recognize that without some presumption favoring proof of infringement, it would be difficult if not impossible to prove infringement by the imported product. As a result, any legislation making such an importation an infringement could be virtually ineffective without such presumption.

There were two major considerations opposing enactment of such a rebuttable presumption: (1) the burden of persuasion in the United States should remain where it has traditionally been placed, on the patentee; and (2) the presumption could result in undue hardship because purchasers and users in the U.S. may well have no knowledge and no means to effectively determine how the product was made, and even with a limitation on the damages that could be assessed against them, such persons could be unfairly subjected to infringement decrees when the product was not, in fact, produced, by the patented process.

The argument concerning tradition would have merit were it not for the fact that the circumstances surrounding the question of infringement would not be those that have been traditionally encountered if the proposed process patent legislation is enacted. In the past, infringement has resulted from acts committed in the United States and, therefore, subject to discovery under our court procedures. If the acts constituting infringement are not performed in the United States and the perpetrators of those acts are not subject to United States discovery proceedings, the patentee would be powerless to determine if an infringement has occurred. It would only be the foreign manufacturer who knows for sure what process was used in producing the imported product. The producer could prove his innocence by disclosing his process

under an appropriate protective order. If he elects not to do so, why should he be allowed to continue to sell his product in the United States at the expense of the innocent patentee who would have exhausted all reasonable efforts to determine if the imported product was, in fact, made by an infringing process? The rebuttable presumption of infringement would put the U.S. policy on an equal footing with many other industrialized countries.

A valid argument could be made that many foreign manufacturers are unfamiliar with United States courts and, therefore, are suspicious of proceedings in our courts. Such a manufacturer, even though he would be innocent of any wrongdoing, might be reluctant to disclose his manufacturing process under a protective order of the court because he would not know how effective the protective order would be. This would be a legitimate concern. However, if such a manufacturer wants to enjoy the benefits of the United States market, should he not also be required to have faith in our court system?

The second argument above has more merit than the first, since an importer may have no knowledge of what process was used to produce the product being imported. However, the importer should have more leverage with the foreign manufacturer than does the patentee. The importer should be able to exert significant influence on his supplier to persuade him that if the process used would not be an infringing one, it would be to the best interest of all parties that the process be disclosed. If the supplier would not disclose the process under these circumstances, it seems reasonable to presume that the process infringes.

Another argument opposing enactment of the rebuttable presumption is that it would be unnecessary in the case where the patented process was practiced in the United States. It is argued that in those circumstances the existence of the presumption would have the negative effect of shifting the traditional burden of proof and perhaps creating fears among innocent United States purchasers and users. The argument that the presumption would not be necessary where manufacture occurred in the United States appears to dispel the notion that the presumption would create fears among innocent purchasers and users. Another way to handle this objection would be to provide that the presumption of infringement would apply only to products made outside the U.S. However, such a limitation appears to be unnecessary.

The fact that the product was manufactured in the United States would give the patentee an opportunity to use the full discovery process to determine if an

infringing process was used. Since this is the case, the presumption would not arise if the enacting legislation follows the proposed resolution because the manufacturer would be subject to the jurisdiction of a U.S. District Court. Under the proposed resolution, there would be no presumption if the patentee could determine the process actually used.

There was an attempt late in the 98th Congress to exclude drugs from legislation on the subject. The objective is a laudable one; i.e., reducing the cost of drugs by making it easier to import them. However, it seems that excluding drugs or any other class of products from the legislation would be counterproductive. There is no rationale for special treatment of drugs.

Most drugs are complex chemical molecules produced by multistep processes. Because of the many steps involved, the overall yield might be relatively low. Improvements in the process can result in substantial savings in manufacturing costs, leading to a lower cost of the drug.

Therefore, it seems that research directed to process improvement in the manufacture of drugs should be encouraged rather than discouraged. The basic purpose of the patent system is to provide an incentive to make and disclose inventions, including alternative and possibly improved ways of making products, such as drugs. The exclusion of drugs from the type of process protection envisioned by this proposed legislation would discourage research directed to process improvements. Or, if process improvements were made, they would be maintained as trade secrets rather than patented. This result is also undesirable since it prevents disclosure of worthwhile technology.

With respect to the "innocent purchaser" issue, the ABA favors some type of notice requirement before a purchaser can be held liable for damages. The issuance and content of a process patent may give no hint to the public that a particular product was produced by any given process, and it is clearly not a satisfactory solution to presume that the patent itself provides fair notice in these circumstances. Since the aim of the provision is to protect the innocent purchaser, who has no knowledge of the alleged infringement and perhaps no effective way to determine by what process the article he purchased was made, the conflicting choices appear to be most satisfactorily resolved by a requirement that the patentee give actual notice to the "innocent purchaser" before he can recover damages from the purchaser.

In addition, there already exists a considerable body of decisional law interpreting and applying the "notice" requirement of 35 U.S.C. §287, which applies to patented

articles and products. Parity of the notice requirements in the proposed legislation with the notice requirement of Section 287 is likely to provide precedential benefit and eliminate uncertainties and confusion that could arise from the existence of a plurality of differing "notice" requirements applicable to the purchase and use of manufactured articles and products. It should be noted that under 35 U.S.C. §287, the mere filing of a complaint against the infringer constitutes notice.

Section 337 of the Tariff Act of 1930 (19 U.S.C. §1337) provides for actions by U.S. citizens in the International Trade Commission (ITC) to obtain exclusion of products from abroad which infringe U.S. process patents. The ITC cannot award monetary damages for infringement. Actions under Section 337, however, are unnecessarily complicated by reason of the requirement in the law to prove that the importation of the infringing articles substantially injures a U.S. industry which is "efficiently and economically operated".

S.539, S.568 and S.573 have been introduced in the 100th Congress and would provide process patent protection generally in accordance with the 1986 resolution of the American Bar Association. These bills would apply only to products produced or imported after enactment.

The American Bar Association believes that there is an important need for such process patent legislation in order to bring the patent laws of the United States into line with the patent laws of other countries. It is important to recognize that such legislation would assist in protecting jobs in the United States against encroachment from abroad.

## CONCLUSION

This completes my Statement on behalf of the American Bar Association. I am very appreciative of the opportunity to present these views, and I thank the Subcommittee on behalf of the American Bar Association.

# Statement of the National Association of Chain Drug Stores, Inc.

SENATE JUDICIARY COMMITTEE

SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS

PROCESS PATENTS AMENDMENTS OF 1987

APRIL 27, 1987

NACDS
National Association of Chain Drug Stores, Inc.
P.O. Box 1417-D49
Alexandria, Virginia 22313
703-549-3001

The National Association of Chain Drug Stores, Inc., (NACDS) deeply appreciates the opportunity to provide the following testimony for the record with respect to the Process Patent Amendments of 1987 (S. 568) which is under consideration by the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks.

Founded in 1933, NACDS is a non-profit trade organization which represents the management of 171 corporations that are operating in excess of 20,000 retail drug stores and pharmacies throughout the United States. Collectively, our corporate members were responsible for an estimated $30 billion in retail sales in 1986 and more than 540 million prescriptions were dispensed to consumers by drug chains during this same period.

Members of the National Association of Chain Drug Stores, range in size from operations with only four retail stores to companies with more than 1,900 retail outlets. Thus, our statement reflects the view of both small businesses and large corporate entities. We are grateful to the Subcommittee for allowing us to file this statement on an important issue that has major implications to retailers.

The need to strengthen our process patent laws is not a unique observation of the 100th Congress. Recommendations in 1966 by the Johnson Administration, in 1979 by the Carter Administration and in 1985 by the Reagan Administration all suggested the need and desireability for stronger process patent legislation. NACDS wholeheartedly supports this objective which will protect domestic patent holders from foreign manufacturers that are taking a free ride by using expensively developed patented processes without proper authorization. During the 99th Congress, NACDS endorsed the need for such legislation while pointing out our concerns on how the proposal could adversely affect retailers. Prior to adjournment of the last Congress, a very acceptable compromise (S. 1543) was fashioned by the Senate Judiciary Committee and adopted by the full Senate. This bill reflected a carefully crafted balance that addressed the concerns expressed by domestic patent-holders, generic pharmaceutical companies, brand-name manufacturers and retailers such as NACDS. We worked hard for enactment of S. 1543 because it was a fair bill that would not result in an undue burden to retailers.

In our view, S. 568 as introduced by Senators DeConcini and Hatch embodies all of the critical principles from S. 1543 including two very important issues to retailers. First, S. 568 would provide for greater enforcement protection to U.S. Patent Holders. Secondly, the legislation is written in such a manner that it correctly discerns the fact that retailers are innocent purchasers in the marketplace. In our industry, the typical retail drug store offers 12,000 different products for sale to consumers, and a corporate drug chain during the course of a year will conduct business with some 3,000 manufacturers, vendors and suppliers. With these overwhelming numbers and diverse product mix, it is impossible for our retailer members to verify the legitimacy of all the products that we purchase and offer for sale in our stores. By the same token, we do not have the expertise or knowledge of how a particular product is made.

Retail drug stores sell everything from basic products such as household supplies and paper goods to the more highly sophisticated items including appliances, recording tape and cameras. Our members do not have the luxury of having a multitude of patent attorneys to review all of the products that are sold in drug stores. Such a situation would be ideal, but with razor-thin profit margins of less than 3 percent, corporate drug chains cannot afford to maintain such legal talent. Therefore, the innocent purchaser provision as contained in S. 568 is terribly important because it would not hold a retailer liable for unknowingly having purchased an infringing item.

Of equal importance to our members, S. 568 also grants a reasonable grace period that will allow a retailer an opportunity to sell off its inventory of an infringing product following notification from the patent holder. Under this provision, the retailer agrees to stop purchasing the infringing products and disclose to the patent holder his source of supply. S. 568 calls for a grace period of 18-months, a temporary reprieve which reflects traditional business practice for the disposal of inventory that has accumulated through previously placed orders prior to being notified by the patent holder. Additionally, the 18-month grace period takes into consideration the fact that retailers purchase many seasonal items way in advance of the time that the products will be received and actually placed on store shelves for sale to consumers. Therefore, the grace period provision in our opinion is absolutely essential to the retailing community in order to minimize disruption of business following notification.

Upon the introduction of S. 568 on February 19, 1987, Senators Hatch and DeConcini both made statements for the record. Senator Hatch indicated that S. 568 is the product of many hours of negotiation while Senator DeConcini emphasized that the legislation is among the highest priorities facing his Subcommittee on Patents, Copyrights and Trademarks. In view of all the disparate views that are delicately accommodated in S. 568, we hope that the legislation can be expeditiously approved by the Subcommittee. NACDS supports S. 568 because it is fair to retailers and will help to improve American's competitive position in world trade.

On behalf of our 171 corporate members, we hope that our statement will be given careful consideration. Thank you.

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HOWARD J. CHURCHILL (1908-1983)

March 31, 1987

Senator Dennis DeConcini
Senate Office Building
Washington, D.C.

Re: S.568 and S.573

My Dear Senator:

With your kind permission in your letter of March 24, 1987, I would like to take advantage of your willingness to have me submit a statement for the Official hearing record.

I have been practicing patent law for many years and have a wide familiarity with process patents as they presently exist and I am familiar with the various discussions and publications relating to process patents and I would like to devote my statement to that specific subject after noting that the subtitle of the above Bills includes the word "overseas" from which I conclude that the Bills exclude countries contiguous to the United States such as Canada and Mexico and that the use of the word in the Bills was intentional; if not consideration might be given to changing the word to "foreign".

For the information of the Subcommitee which you Chair, my practice is primarily related to Chemical, pharmaceuticals and medical inventions and patents to which area I believe the above Bills are particularly germane. I am a member of leading legal and scientific societies including The American Bar Association, The American Chemical Society, The American Institute of Chemists, Inc. as well as having been an Examiner in the U.S. Patent Office.

I would like to focus my statement on the word "process" which is the major consideration of the above Bills.

The term "process" is defined in 35 U.S.C. 100(b) which states that it "means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter or material." With this as a premise it will be apparent that the term "process" is very broad and encompasses many possible situations. On the basis of that definition of the term "process" the amendment as proposed to 35 U.S.C. 154 clearly covers extremely wide interpretations giving rise to the possibility that the use of the term in the proposed legislation might cover more than is authorized by Article I, Section 8 of the Constitution of the United States from which all patent rights flow. Since the Constitution

gives Congress the power to promote the progress of science and useful arts by securing for limited times to ***inventors the exclusive right to their respective ***discoveries, the wording of the Constitutional provision may have well given rise to an interpretation of the above Bills which goes beyond the Constitutional authority. It could be argued that "exclusive rights" covers only what the inventor has discovered and patented. It would seem logically to follow that the inventor of a product patent (using the term product broadly in the sense of 35 U.S.C. 101) is not by the Constitutional authority granted to Congress entitled to exclusive right to the process for making such product. This point is raised for purposes of consideration only as presumably it has been already considered in the drafting and preliminary hearings on the above bills but nevertheless the point would seem to be viable and possibly requiring restudy. By analogy where the inventor has made a process invention and has obtained a patent for his process he has clearly not invented a product and indeed his patented process may be an improvement process for the more efficient and economical production of a known or old product. It is also the case in my experience that a process patent may be granted to an inventor under special circumstances such as in the antibiotic or medicinal field to produce a product of unknown composition i.e. a substance having useful properties such as for medicinal purposes but the chemical structure of which is unknown or has not yet been able to be determined, this being the case with certain new pharmaceuticals and medicinal products made by procedures involving genetic engineering. I am thinking in this context since I personally handled the prosecution of a very basic and exceedingly important substance called, for lack of a more specific name, Interferon. While there are at least 4 and probably more such substances it has not yet been elaborated in the sense of being able to set forth a chemical structure. The knowledge in the Interferon patent has proliferated in many directions and has contributed to a wide variety of research products which ultimately could very well have extremely valuable properties since it is highly antiviral. This is merely one instance of patents which are essentially process patents and which describe more than one way of making the product. In that particular Interferon patent situation the Patent Office allowed several process claims for making Interferon but for other reasons worked out between the Patent Office's Examiner and the present writer product claims were substituted in view of the publication of a book entitled INTERFERONS.

To extend the scope of a process patent i.e. a granted patent which defines the invention in terms of a series of process steps is an extremely important extension of patent rights which requires the most thorough consideration not only because a process patent inventor is being given rights which he did not have before and which are not authorized by Title 35 of the U.S. Code but because the extension of such rights may be in conflict with the Constitutional provision.

There is another type of situation with respect to a process patent which should be taken into account and that is what is known as a method of treatment claim. This can be exemplified by a claim reading along the following lines:

> A method of treating hypercholesteremia (as an example only) which comprises administering to a patient in need thereof an effective amount of a designated compound or a pharmaceutically acceptable salt thereof together with a carrier material.

It will be observed that this type of claim does not

lend itself to be extended to the resulting product which is a patient having the medicament in his/her system sufficient to overcome the disorder for which the treatment is directed.

There is still another type of situation which needs consideration with respect to the above Bills and that is where the process claim in the patent only goes so far as to claim an intermediate. The intermediate would then have to be reacted chemically with an agent which converts it to final useful form since the intermediate has little or no effectiveness. This is well illustrated by a process for making the intermediate of a penicillin such as ampicillin or amoxycillin where the process results in the intermediate having for example an $NH_2$ group which upon acylation or the like results in the final product which has the desired medicinal activity.

Both of the above Bills refer to section 271 (a)(2) and a Court action brought thereunder and no special comment is necessary since the purpose of the bills in this regard is clearly and simply stated.

The purpose of the writer's statement for the hearing record is directed to the word "process", to its definition in Title 35 of the U.S. Code, to its relevance to the Constitutional provision and to the broadness of the word itself. It is mentioned in part that this newly proposed legislation will raise numerous legal and interpretative questions which have not up to now been resolved and which find no clear support in judicial decisions. The purpose of the Bills is something which will introduce profound changes in the patent law and the desirability of such changes requires deepest thought. The Bills also involve economic considerations indirectly and the state of good health and otherwise of certain U.S. industries. With all due respect to the wisdom of the Congress the writer's statement based on many years of patent practice is disturbing even though the overall concept of the bills seeks to protect U.S. industries which might otherwise be adversely affected by extending the meaning of the word "process" to cover patent coverage to the product produced by the process patent. This is a novel concept for U.S. patent practice and litigation but is not novel with respect to the practice in some foreign countries which interpret process patents as covering and protecting the product produced by the patented process. This has not been U.S. law regarding process patents.

It is recognized that the patent system as a whole is in a state of flux in that various individuals and organizations are proposing to revise or modify the patent law for the greater protection of U.S. individuals, companies and industries and it is agreed that improvements in the existing patent law are desirable to meet the changing times and advancing technologies. Just exactly what those changes should be are undecided although conformity in the interpretation of patent questions is one of the main objectives of the Court of Appeals for the Federal Circuit (CAFC) which has in fact and in a real sense codified the settlement of patent disputes with the apparent intent of creating uniformity which does not presently extend to the various Judicial Circuits and which to some extent varies with individual judges.

While the objective of the above Bills seems clear and is stated in a simple and direct manner, it should be taken into account that there are patents which in a sense could be called hybrid since they are in the ostensible form of product patents and yet contain process limitations. The question

arises as to such patents as to whether the production of the patented product by a process outside the scope of the process limitations of the patent claims is intended to be covered by the above Bills. This situation arose in the decision In Re Hallman 210 U.S.P.Q. 609 which is a decision of the CCPA, the predecessor of the CAFC, and which decision held in part "product claims may be drafted to include process steps to wholly or partially define the granted product and to the extent that the process limitations distinguish the products from the prior art they must be given the same consideration as traditional product characteristics." Another question which could arise is where a compound patent contains a claim directed to the compound "as isolated by known techniques". This was the case in patent No. 4,127,571 granted November 28, 1978 which while technically a product patent involves process steps giving rise to the question as to whether "known techniques" for producing a new and useful compound falls with the contemplation of the above Bills.

The opportunity to express the writer's views as outlined above is greatly appreciated. The writer is also a strong supporter of the patent system while recognizing that the time has come to make changes. In the writer's capacity of Chairman of the Patents Committee of The American Institute Of Chemists, Inc., he is highly desirous of seeing worthwhile amendments made to the patent laws without conflict with International provisions for obtaining patents such as the European Patent Act and the Patent Cooperation Treaty. The writer looks forward to progress of the above bills and related HR Bills such as introduced by Representative Rostenkowski.

Upon passage of the Bills, it can be concluded that each situation will probably require solution on a case by case basis.

Respectfully submitted,

Albert L. Jacobs

# Patent and Trademark Office Society

P.O. BOX 2089 • ARLINGTON, VIRGINIA 22202


The Honorable Dennis DeConcini
United States Senate
Washington, D.C. 20510

May 5, 1987

Dear Senator DeConcini:

The Patent and Trademark Office Society (PTOS) thanks you for this opportunity to offer our comments regarding S.568 and S.573.

The PTOS supports strong and easily enforced patents. The proposed legislation will enhance protection for process patents and therefore is endorsed by the PTOS Board of Directors.

We support the proposed amendment to 35 USC 287 in S.573 which grants courts equitable discretion for the disposal of infringing goods, taking into consideration the "good faith and reasonable business practices demonstrated by the infringer". This is a reasonable compromise with those who have opposed process patent reform. The inclusion of this feature will protect "innocent" infringers without forcing the patentee to accept a de facto compulsory license. This is consistent with U.S. efforts to harmonize its laws with those of its major trading partners and to discourage third world nations from adopting compulsory licensing.

We also support the legislation's provision for a reasonable and balanced basis for presumption of infringement. The presumption in necessary since the laws of most foreign countries do not have adequate discovery procedures.

We feel it may be necessary to include a "grandfather" clause because of Constitutional issues which may arise with respect to pre-existing good faith contracts.

We commend you for your efforts to strengthen U.S. intellectual property rights.

Sincerely,

Richard T. Stouffer

Richard T. Stouffer
President, PTOS

**Dedicated to the improvement and appreciation of the United States Patent System**

PARISH CHEMICAL COMPANY
145 NORTH GENEVA ROAD, OREM, UTAH 84057 — PHONE (801) 226-2018 — TELEX 453-136

FINE CHEMICALS
CONTRACT RESEARCH
CUSTOM SYNTHESIS
SCREENING SAMPLES

April 27, 1987

The Honorable Orrin Hatch
United States Senate
SR-135
Russell Senate Office Bldg
Washington, DC 20510

Dear Senator Hatch:

As the president of a research and development and chemical manufacturing company, I am very concerned about your position on pending process patent legislation. For many years foreign competitors have made a practice of pirating U.S. patented process technology which is used by the foreign manufacturer to produce goods ultimately sold in the U.S. This practice is unfair to both the U.S. patent holder and the chemical process industry. It is difficult for me to compete with foregin manufacturers that have many years of experience with a U.S. patented process that I have been prohibited to use until the patent runs. It is even more difficult when the foreign competition is allowed to develop a U.S. customer base years in advance of the U.S. competitors. The current practices of many foreign manufacturers are grossly unfair to American business and must not be allowed to continue.

My personal feeling is that S568 contains many features which are too weak and compromising to give effective protection against the excessive abuse of U.S. process patents by foreign manufacturers. Specifically we would like to see legislation which; 1) puts an immediate stop to any futher imports, use, or sale of infringing material upon notification; 2) provides damages for any use, sale, or import of infringing material prior to as well as after notification; 3) sets reasonable standards for notification and demonstration of infringment. The present substantial likelihood requirment in S568 is an unreasonably high standard. Process technology listing provisions presently under consideration also place an unfair burden on the manufacturer and compromise the intergrity of the manufacturers proprietary position. Any such provisions will only make it easier for our competitors to pirate American technology.

We import and use foreign goods as well as manufacture in competition with foreign suppliers. We have also been involved in the bulk generic drug manufacturing business and have delt with foreign manufacturers as well as brokerage firms importing foreign manufactured goods. In our experience the foreign manufacturers are well aware of what they are doing. Most importers and users are also either well aware or could easily make themselves aware of potential infringment situations. Especially with pharmaceuticals, foreign manufacturers often represent that the goods supplied are manufactured with the same or a similar process as that used by the major U.S. manufacturer. Even when such representations are not made, the foreign duplication of a U.S. process is a generally recognized practice in the industry and it is not conducted in the blissfull ignorance you have probably been led to believe.

There is a pressing need to place some burden on the importer and user to obtain certification or assurance from their suppliers that imported goods are not infringing. Although none of the present bills go as far as we would like, S.573 and S.539/H.R.1155 are much better than S568. I think it's time to write a bill that will generate some respect for the American patent and for Amercian process technology. Please give us a chance to compete on a fair basis.

Sincerely,

W. Wesley Parish,
President

cc: Senator DeConcini
Senator Lautenberg